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18 April 2009

# Dispensing justice?

The profession speaks out on errors

See page 8


Nasacort Allergy is now available for pharmacy. Its thixotropic[1], once-a-day formulation stays where it's sprayed for maximum effect against hayfever symptoms – and with no strong odour or taste, patients prefer it over Beconase® and Flixonase®[2,3]. Give them Nasacort and help avoid problems whenever hayfever's around. For more information about Nasacort Allergy, and copies of training materials and point-of-sale items, please contact your local Laser Healthcare Pharmacy Business Manager or call 01202 780558.




Stays where it's sprayed

**NASACORT ALLERGY NASAL SPRAY PRESCRIBING INFORMATION**

**Presentations:** Each bottle of Nasacort Allergy Nasal Spray contains 3.575 mg triamcinolone acetonide and provides at least 30 actuations each containing 55 micrograms of active compound after initial priming. **Indications:** Treatment of the symptoms of seasonal allergic rhinitis. **Dosage and Administration:** Patients aged 18 years and over: recommended dose is 220 micrograms as 2 sprays in each nostril once daily. Once symptoms are controlled patients can be maintained on 110 micrograms (1 spray in each nostril once daily). The minimum effective dose should be used to ensure continued control of symptoms. Children: not recommended for children or adolescents under 18 years of age. Medical advice should be sought if symptoms worsen or persist after 14 days treatment. **Contraindications:** Hypersensitivity to any of the ingredients of this preparation or an infection in the nose. **Warnings and precautions:** Impaired adrenal function, patients taking steroids should consult their doctor before using this product, recent nasal surgery or prolonged nose bleeds, pregnancy or lactation. There are rare reports of localised candida albicans infections in which case product should be discontinued and appropriate therapy instituted. This product should not be used for longer than 3 months without consulting a doctor. **Side-effects:** The most commonly reported adverse reactions are rhinitis, headache and pharyngitis. Respiratory disorders: epistaxis, nasal irritation, dry mucous membranes, sinus congestion and sneezing; rarely, nasal septal perforations. In clinical trials these adverse reactions with the exception of epistaxis, were reported at approximately the same or lower frequency as placebo treated patients. Skin or subcutaneous disorders: rarely allergic dermatitis, urticaria, pruritus and facial oedema. Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods. **Legal Category:** P.

[illegible] February 2009. NAS 09/1091

**Product Licence Number:** PL 04425/0605 **Recommended selling price:** £4.95. **Refer to Summary of Product Characteristics for full prescribing information. Further information is available from the Marketing Authorisation holder: sanofi-aventis, One Onslow Street, Guildford, Surrey, GU1 4YS. Date of Revision of Prescribing Information: October 2008.**

**References:** 1. Nasacort Summary of Product Characteristics, 2008. 2. Lumry W et al. A comparison of once-daily triamcinolone acetonide aqueous and twice-daily beclomethasone dipropionate aqueous nasal sprays in the treatment of seasonal allergic rhinitis. Allergy Asthma Proc 2003;24(3):203-10. 3. Stokes M et al. Evaluation of patients' preferences for triamcinolone acetonide aqueous, fluticasone propionate, and mometasone furoate nasal sprays in patients with allergic rhinitis. Otolaryngol Head Neck Surg. 2004; 131(3):225-31.

**PIP code 342-5501.**

**Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk Adverse events should also be reported to the sanofi-aventis Drug Safety Department on 01483 505515.**

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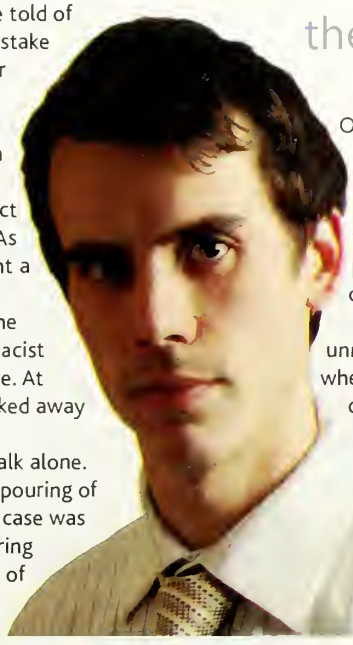
## Comment from the Editor

**Much of the conversation between C+D and** Elizabeth Lee this week will never be aired. Working together, and with the wishes of the former locum, we have published only snippets of a phone call that hammered home the brutal, human cost of laws that make dispensing errors a crime (p4).

Yet, the haunted voice on the other end of the line was not one you might associate with a convicted criminal. A distraught Mrs Lee told of her total remorse over the mistake that sent beta-blockers rather than steroids to an elderly woman, who later died.

The mistake, punished with a suspended jail term, was honestly made and not a direct cause of the patient's death. As soon as the error came to light a woman with an otherwise immaculate record decided she would never work as a pharmacist again. What a desperate waste. At just 30 years old Mrs Lee walked away from pharmacy.

But, at least she will not walk alone. There has been a massive outpouring of support for Mrs Lee since her case was reported last week. Her suffering has struck a chord with many of you who know that there but for the grace of God (go I).



"There's been more response to Mrs Lee's ordeal than any other story we've covered in the past four years"

Our website, mail box and phone lines have been flooded with well wishers. There's been more response to Mrs Lee's ordeal than any other story we've covered in C+D in the past four years. It's stirring stuff to see the pharmacy family come together and fight for one of their own.

Your messages of support have not gone unnoticed. Mrs Lee herself appeared touched when told that so many former colleagues felt compassionately towards her. The incident has also put the case for decriminalising one-off dispensing errors firmly on the political agenda (see p8). It seems some good may yet come from this heart-breaking story.

**Max Gosney, News Editor**

## Contents



C+D TABPI Awards 2008
Winner for news coverage

# Sentenced locum: my deep remorse over dispensing error

Pharmacists voice support for Mrs Lee and echo call to decriminalise dispensing errors

Max Gosney

**Elizabeth Lee has told C+D of** her deep remorse over the dispensing error that was punished with a suspended jail sentence (C+D, April 11, p6).

The former locum said she had made a genuine mistake and repeated her vow never to practise again.

In 2007, Mrs Lee dispensed propranolol instead of prednisolone to 72-year-old Carmel Sheller, who later died.

Mrs Lee bore no legal or factual responsibility for Mrs Sheller's death, the courts heard.

However, she was sentenced under terms of the 1968 Medicines Act that class dispensing errors as a criminal offence.

Mrs Lee declined to make any further comments.

C+D has been passing on messages of support to the 30-year-old as the case triggered heavy sympathy among fellow pharmacists this week.

The C+D website had been flooded with postings voicing support for Mrs Lee.

Bob Dunkley, a Leeds pharmacist posting on the C+D website, said: "If Mrs Lee's case is to be written into case law then we are all doomed. It would seem that whilst judges can make mistakes, and continue to make mistakes, we as pharmacists are subject to one strike and you're out."

Many pharmacists repeated calls for dispensing errors to be decriminalised following Mrs Lee's ordeal. Shamir Patel, superintendent pharmacist at the North Meols Pharmacy chain, said: "It's quite worrying that the RPSGB hasn't pushed for a change in the Medicine's Act earlier [to stop this]. I'm looking for them to take this up extremely quickly."

The RPSGB said last week it had urged the MHRA to decriminalise errors as a priority.

The judge presiding over Mrs Lee's case said a prison sentence had been imposed to mark the gravity of the offence.

Should dispensing errors be a criminal offence?
**Turn to page 8**

Photo: Ed Willcox, Central News

## Send your messages of support to Elizabeth Lee

C+D is offering pharmacists the opportunity to send messages of support to Elizabeth Lee. If you would like to express a view, send us your thoughts by emailing mgosney@cmpmedica.com or leave a comment at www.chemistanddruggist.co.uk/news

# Keep rise in regulation and leadership costs at inflation

**The cost of the RPSGB's** regulatory and professional leadership roles in 2010 should not exceed the current fee by more than the rate of inflation, a financial report has found.

The investigation, carried out on behalf of the RPSGB and the Department of Health, concluded that it is possible to set a combined fee without a significant increase.

The fee proposal was revealed in minutes from the latest meeting of the Pharmacy Regulation and Leadership Oversight Group (PRLOG), the group charged with establishing a new pharmacy regulator.

At the current rate of 3.2 per cent inflation, the combined fee would rise from £413 to around £426. A final decision will be made in July by the RPSGB, and will follow a consultation process making place between April and June.

The Society is expected to make an announcement on fees early next week.

The PRLOG meeting outlined plans to pay the General Pharmaceutical chair £48,000 per year and council members £12,000 a year.

Key recommendations for the new regulator included:

- Non-statutory committees to be kept to a minimum with three groups recommended on audit, remuneration and appointments
- No overriding need for an education committee. Other regulators have coped without one, PRLOG said. **JC**

## No SOP review following Lee case

Tesco will not review its standard operating procedures following the Elizabeth Lee case, the supermarket firm has confirmed.

Mrs Lee's legal team had linked "long and arduous shifts" to the dispensing error, which occurred at a Tesco pharmacy in Windsor. When asked if Tesco would review working procedures in light of the case, a spokeswoman said: "No. We have very high standards in place. She was a locum pharmacist and she chose to work the hours that she did."

She added: "We would like to stress this is an isolated incident."

Mrs Lee, received a three-month suspended sentence for dispensing beta-blockers instead of steroids to a 72-year-old woman who later died.

Tesco's SOP recommended different people dispense and check prescriptions. Where one pharmacist did both they should take "mental breaks", the court heard.

Meanwhile, it remains unclear whether Mrs Lee will face disciplinary action from the RPSGB over the incident.

A spokesperson said: "The Society is aware of the issues pertaining to Elizabeth Lee and is currently considering next steps".

The RPSGB has previously said it could not comment on Elizabeth Lee's case because it would be "required to deal with the matter" in due course due to its regulatory responsibilities.

Mrs Lee resigned from the register as soon as the error came to light in August 2007. **JC**

Should Tesco review its SOPs?
**mgosney@cmpmedica.com**

# Boots pharmacist's CPR skills save baby girl

First aid training put into practice on five-month-old with breathing difficulties

Max Gosney

**A Boots pharmacist has saved** the life of a five-month-old baby who stopped breathing while her mother shopped in the store.

Krinal Shah stepped in to give the child CPR while paramedics rushed to the pharmacy on Islington high street.

With help from staff at the 999 call centre, Ms Shah resuscitated the baby girl for 10 minutes.

Ms Shah said: "It was about 4pm on a normal day when the mother noticed the baby was quite floppy and she ran over with the baby to the pharmacy."

"We called the ambulance straight away because the baby wasn't breathing. I gave the phone to the store first aider and she relayed the information to me while I carried out CPR."

Ms Shah had picked up the CPR skills on a training course she attended just a month ago as part of anaphylaxis training for giving influenza and HPV vaccinations. Paramedics have since visited Ms Shah in store to thank her.

She added: "At that moment instinct took over – I did know how to carry out CPR but I'm glad I had back up."

Krinal Shah: first aid and resuscitation training ensured she was prepared

Ms Shah, who has worked as a pharmacist for three years, says she was overjoyed when she found out the baby had not only survived but was fit and well.

"I would definitely recommend everyone keeps up with their first aid and resuscitation training, if I hadn't had that it would have been very difficult."

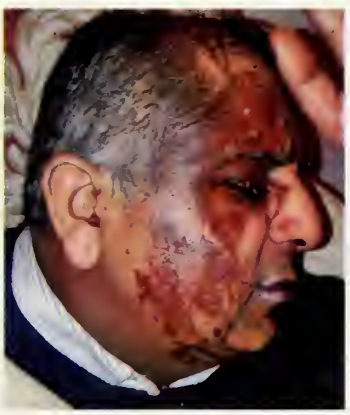
# Two blinded in acid attack

**A London pharmacist and his** assistant have been left fearing for their eyesight after being blinded and burned in an attack while closing their pharmacy.

Pharmacist Mukesh Waghela, 49, and assistant Jilan Miah, 17, were leaving Wagpharm pharmacy in Stratford on March 30 when they were assaulted by two men with a corrosive spray, suspected to be hydrochloric acid.

Mr Waghela and Mr Miah were blinded before being kicked to the ground and mugged.

Mr Waghela said: "As they tried to squirt [the liquid] into my eyes I wasn't going down, so [the robber] kicked the back of my legs. As I fell to the ground he started yelling 'Where's the stuff? You're obstructing me!' and put his hand into my jacket."


Mukesh Waghela: rushed to hospital

The two men escaped with cash. Mr Waghela and Mr Miah were rushed to hospital where they were treated for eye damage and burns.

Mr Waghela said he had still not recovered from his ordeal. "I'm still attending hospital... my eyesight isn't clear, it's still fuzzy. The skin is still healing, but it's a long way from perfect.

"If I can gain my eyesight back I'd be the happiest man. Each day you think it's going to get better, but it starts to play on your mind. You think, if you can't work, what are you going to do?"

The attack is the fifth incident at the pharmacy in the past few years. Police were unable to confirm if any suspects have been arrested. **CC**

Do you feel safe in your pharmacy?
cchapman@cmpmedica.com

## News in brief

### Novartis MS treatment

Novartis has launched Extavia (interferon beta-1b), powder and solvent to treat early and relapsing-remitting forms of multiple sclerosis. The recommended adult dose is 250mcg in 1ml of reconstituted solution injected subcutaneously every other day.
http://www.medicines.org.uk

### GP inquiry

A major inquiry into the quality of service provided in general practice in England has been launched by think tank The King's Fund. It is hoped the six-month research project followed by a consultation with health professionals, including pharmacists, will produce a series of parameters against which to measure services.
www.chemistanddruggist.co.uk

### 'Flabjab' provider fined

A man has been ordered to pay more than £800,000 for the illegal advertising, sale and supply of unlicensed medicine Lipostabil. Duncan Williams, of Barnt Green, Birmingham, was told at the Old Bailey to pay the confiscation order within six months or face a four-year jail term.

### Sinemet shortage

Manufacturer Bristol-Myers Squibb Pharmaceuticals is experiencing limited supply of Sinemet (co-careldopa). Affected presentations are Sinemet CR tab 50/200mg, Sinemet Plus tab 25/100mg and Sinemet tab 12.5/50mg. All other presentations are expected to remain in stock.

### Pull poorly paid services

Community pharmacists should withdraw services that are not being fairly remunerated, the Avicenna conference in Las Vegas has heard. Birmingham-based contractor Noordin Ladha, who has rolled out a range of services, urged colleagues to demand a fair price from the NHS.
www.chemistandruggist.co.uk

### CAMRx convention

This year's CAMRx convention will be held at The Grand Harbour Hotel in Southampton and the Beaulieu Transport Museum on June 27 and 28. Members are advised to book early.

## Dispensary TALK

**Should dispensing errors be decriminalised?**

"I think it should be decriminalised, yes. It really depends on the context the error was made, but if the pharmacist has followed all procedures possible it's human nature, everyone makes errors, and it shouldn't be criminalised."
**Hatul Shah, Carter Chemist, Middlesex**

"That's a tough one. I think it depends; each case should be individually assessed, rather than just having one rule for it."
**Jennifer Reid, Fairoak Pharmacy, Streatham, London**

### WEB VERDICT:

Yes 86%
No 14%

**Armchair view:** The respondents have weighed up the evidence and delivered their verdict: the majority believe dispensing errors have no place in a criminal court.
**Next week's question:** Have you ever made a dispensing error? Cast your vote at **www.chemistanddruggist.co.uk**

# Recession is stifling business sales market

Goodwill values plummet and pharmacy sales fall 30 per cent, say financial experts

Zoe Smeaton

**The economic downturn has had** a negative impact on sales and prices of pharmacy businesses, financial experts have said.

Umesh Modi, a specialist pharmacy financial advisor at Silver Levene, said in the last 12 months he had seen the goodwill values of pharmacies fall by 20 to 25 per cent compared with values achieved in the first half of 2007.

And he said the number of pharmacy sales being agreed had fallen by around 30 per cent.

Mr Modi blamed market conditions, category M, threats from 100-hour pharmacies and eroding gross profit margins for the fall in goodwill values.

Mr Modi said wholesalers were "simply not prepared to guarantee loans if goodwill prices are unreasonable". He added that sellers' expectations of prices were still high after strong prices in the last few years, making it difficult to agree on sale prices.


Pharmacy Partners, which offers working capital for pharmacies, said it has also seen a drop in the number of sales being agreed in recent months. And the company has seen increase in the number of requests from pharmacies for working capital.

Andy Harwood, associate director at the company, said as the terms on bank and wholesaler loans were tightening up, pharmacies were struggling to raise cash.

The company was receiving "more enquiries from bigger retail groups who have multiple outlets and are still being affected by category M", he added.

Need advice on selling your business?
**Beat the credit crunch on p28**

# Avicenna to pilot 'virtual chain'

**The 1,000-strong independent** pharmacy group Avicenna is to pilot a 'virtual chain' model in a bid to help its members become more successful, C+D can reveal.

The trial, to be launched within the next three months, will have six elements that contractors will have to implement. A 'head office' structure will support the trial.

Pharmacists would be able to buy more efficiently, improve sales, reduce administration, deliver new services and improve staff training, said the group. Avicenna will track performance indicators to see how pharmacists comply with the scheme, which will be known as ACE Plus.

The scheme's component elements will be tested in around five to 10 pharmacies before being rolled out to a larger group of 50 to 100 pharmacies.

Feedback from members to the virtual chain concept had been "very positive" said Avicenna CEO Salim Jetha, at the group's annual conference in Las Vegas.

The long-term effects of the planned model would be to raise standards and create more professional pharmacies, he explained. **GP**

## Barriers to first time buyers

**Pharmacists looking to buy** their first pharmacy are suffering difficulty raising finance, a lack of business training and uncertainty over the future direction, Avicenna directors Salim Jetha and Uma Patel claimed.

But pharmaceutical needs assessments by PCTs could provide opportunities, they said. As PCTs can commission services from any provider, new entrants may not need to have 'bricks and mortar' premises and could operate from mobile units, the directors suggested.

Independents looking to raise finance for purchases typically had to have up to a 20 per cent deposit with the rest borrowed at up to 5 per cent above bank base rates, Mr Patel said. **GP**

# LETHAL OBSESSION

Weight loss is a vital part of cardiovascular risk management and weight loss with Xenical can have a significant impact upon key risk factors.[1-5] When you help change their weight, you help change their future.

**Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Roche Products Limited. Please contact Roche Drug Safety Centre on: 01707 367554**

Roche

**PRESCRIBING INFORMATION. XENICAL (orlistat). Indications:** XENICAL is indicated in conjunction with a mildly hypocaloric diet for the treatment of obese patients with a BMI ≥30 kg/m², or BMI ≥28 kg/m² with associated risk factors. Treatment should be discontinued after 12 weeks if patients have been unable to lose ≥5% of their body weight. **Dosage and administration:** One capsule immediately before, during or up to one hour after meals (only 30% of calorie intake from fat). **Contra-indications:** Chronic malabsorption syndrome, cholestasis, breast-feeding, known hypersensitivity to any component of the product. **Precautions:** Monitor anti-diabetic drug treatment. Co-administration of orlistat with ciclosporin is not recommended. Treatment may potentially impair the absorption of fat-soluble vitamins (A, D, E, and K), patients should be advised to have a diet rich in fruit and vegetables. The possibility of experiencing gastrointestinal events may increase when orlistat is taken with a diet high in fat. Caution should be exercised when prescribing to pregnant women. Studies have shown no interaction between orlistat and oral contraceptives, however an additional contraceptive method is recommended to prevent possible failure of oral contraception that could occur in case of severe diarrhoea. Rare cases of rectal bleeding, generally of mild intensity have been reported and prescribers should investigate further if symptoms are severe or persistent. **Drug Interactions:** A decrease in ciclosporin levels has been observed in an interaction study. Co-administration with acarbose should be avoided. INR values should be monitored if patient is on warfarin or other anticoagulants. Reinforcement of clinical and ECG monitoring is warranted if patient is on amiodarone. **Side-effects:** Please consult the Summary of Product Characteristics for full details of adverse events. **Common:** Influenza, anxiety, headache, respiratory infection, urinary tract infection, menstrual irregularity, fatigue and gastrointestinal such as oily spotting, abdominal pain, increased defecation and flatulence. Treatment adverse events in type 2 diabetics included hypoglycaemia and abdominal distension. The incidence of adverse events decreased with prolonged use of orlistat. **Serious:** Very rare cases of increases in liver transaminases and alkaline phosphatase and also cases of hepatitis. Very rare cases of bullous eruptions, diverticulitis and cholelithiasis. Rare hypersensitivity reactions of angioedema, bronchospasm and anaphylaxis. **Legal Category:** POM. **Presentation and Basic NHS Cost:** Xenical 120mg (84 capsules) £33.58. **Marketing Authorisation Number:** EU/1/98/071/003 (84 capsule blister pack). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, UK. Further information is available on request. Xenical is a registered trade mark. **Date of preparation:** June 2007.

**References: 1.** Hollander PA et al. Diabetes Care [illegible] 1294. **2.** Hanefeld M and Sachse G. Diabetes Obes [illegible] 415-423. **3.** Sharma AM and Golay A. J Hypertens [illegible] 1878. **4.** Broom I et al. Br J Cardiol 2002; 9: 460-468. **5.** Torgerson JS et al. Diabetes Care 2004; 27: 155-161.

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**orlistat 120mg**

**Block fat and help change their future**

J9792055T August 2008.

For details on Mrs Lee's case see:
www.chemistanddruggist.co.uk/news

# A criminal mistake?

As passions are aroused over the sentencing of Elizabeth Lee for a dispensing mistake, Chris Chapman asks why one-off dispensing errors can still make you a criminal

We all make mistaks. But the consequences of dropping a letter pale in comparison to the sword of Damocles that hangs above every pharmacist's head: one mistake and your whole world can come crashing down.

Last week, C+D reported the case of Elizabeth Lee (April 11, p6), a former pharmacist whose chosen career now lies in tatters. Mrs Lee made a dispensing error and her patient later died.

The case was tragic, but the 30-year-old pharmacist bore no factual or legal responsibility for the patient's death, the Old Bailey heard.

Despite this, for Mrs Lee, it didn't end with her feelings of guilt and remorse. It didn't even end when she chose to leave the profession. It ended in the dock of a London court, where a judge handed down a three-month suspended jail term. Mrs Lee made one error and now she's a criminal.

And this could happen to any pharmacist in the UK, warns Sandra Gidley MP. She says anyone who claims never to have made a dispensing error is a liar. This is backed up by RPSGB research that in 2006 found there are around 114,000 near-misses and 20,000 dispensing errors in England and Wales every month.

And, according to the blunt instrument of the law, every one of these could lead to jail because dispensing errors aren't a grey area in the eyes of Lady Justice, as section 64 of the Medicines Act 1968 makes clear (see box).

But while it's important to recognise that mistakes are made, Mrs Gidley believes criminalising them in this way goes against the principles of today's NHS.

She says: "If there's a threat of criminal prosecution hanging over somebody for a mistake, then this is counter to the whole ethos of a no-blame culture."

And this threat is undermining the profession's confidence, suggests Berkshire LPC secretary Ralph Higson, who represents the area where Mrs Lee's mistake took place. He says: "It will terrify pharmacists if they make a slight error that somebody is going to jump on them."

Mr Higson's right. It's hard to deliver your best when you're constantly under the threat of criminal prosecution, but it's not as simple as just abolishing the law. The issue is a minefield, as Dr Richard West, chairman of the Dispensing Doctors' Association, recognises.

"There needs to be a balance," Dr West says. "You need a system that's going to catch deliberate misdispensing. But for genuine errors... we shouldn't criminalise those that do it."

Dr West has a point. Play devil's advocate for a moment and it's easy to see why the law is in place; it's there to stop pharmacy's answer to Harold Shipman, or any dispenser tempted to squeeze out profit margins by using substandard medicines.

## What the Medicines Act actually says:

Section 64: *"No person shall, to the prejudice of the purchaser, sell any medicinal produce which is not of the nature or quality demanded by the purchaser...[or] specified in the prescription."*

The real problem is that section 64 of the Medicines Act isn't being used as intended, says David Reissner, partner at Charles Russell solicitors.

He says: "I don't think it was intended by parliament that [section 64] should cover dispensing errors at all... it's been treated as a fallback for prosecutors that can't get a manslaughter conviction. And in my opinion that's wrong."

There is, of course, also a powerful human argument for the law. If someone made a mistake that killed someone you loved, wouldn't you be crying out for justice?

However, justice for the individual should be a matter for the civil courts, says Mr Reissner.

RPSGB president Steve Churton goes further, saying criminal prosecution for one-off dispensing errors should be reserved for matters in the public interest.

Mr Churton says he can "wholly understand" why many would view a jail term for Mrs Lee's mistake as a step too far. "The Society firmly believes such dispensing errors should not be criminal offences and that they should be properly dealt with by the regulator," he says.

Mr Churton pledges that the Society will meet with the pharmacy minister to address the issue. The Society has also called for a change in the law in response to the MHRA's current review of medicines legislation.

Both are welcome steps. But this isn't the first time the Society has tried. In 2006 the Society council met and said it would seek to change the legislation.

It's now 2009. Past demands mean very little to Mrs Lee, or any other pharmacist at a coal face where one wrong move results in disaster.

Dispensing mistakes happen. And even with the introduction of robots and SOPs, the utopian ideal of a world without errors is closer to fantasy than reality.

The Society believes that practising under the threat of prosecution can only serve to hide these one-off errors. Now only a change in the law to decriminalise dispensing errors will allow us to learn from our mistakes rather than face criminal charges because of them.

# Confusion over lactose intolerance means many are unnecessarily avoiding dairy

More and more of your customers will be aware of food allergies and intolerances, yet there is still confusion surrounding the causes and symptoms of lactose intolerance (LI) and as a result they may be unnecessarily cutting out dairy from their diets altogether.

## LI and Dairy Allergy Explained

The incidence of LI or lactase deficiency is one in seven,[1] but many people are experiencing discomfort on a daily basis from consuming lactose, often mistaking it for what they believe to be dairy intolerance, without realising that it could be the lactose causing their discomfort.

Furthermore, confusion over the meaning of 'dairy intolerance' is causing people to unnecessarily eliminate dairy products from their diet. Avoiding milk and milk products altogether, without a carefully managed diet, can result in long term health problems such as osteoporosis, caused by a lack of calcium. It is therefore important for the lactose intolerant customer to eat calcium rich foods such as fish with soft bones, fortified juices, green leafy vegetables, fortified breakfast cereals and if necessary, supplements. Lactofree's range of milk, cheese and yogurts are also a good source of calcium. It is also important to ensure an adequate intake of vitamin D to aid calcium absorption.

With help and guidance from pharmacists, LI can be easily managed and symptoms can be controlled through making very small changes to diet.

## Symptoms

The most common symptoms of LI (the body's inability to digest lactose, the natural sugar found in milk) appear between 30 minutes to 2 hours after ingesting lactose. The severity of symptoms differs from person to person and, although not life threatening, they can have a real impact on their quality of life.

## The most common symptoms include:

- Nausea
- Abdominal pain
- Bloating
- Flatulence

These symptoms are not limited to LI, so the condition can often be misdiagnosed as a dairy allergy or intolerance, or irritable bowel syndrome (IBS). It is estimated that up to 80% of people diagnosed with IBS in fact have lactose intolerance.[2]

## Testing for LI

A reliable test for establishing LI is the Elimination Diet, developed by Lactofree and reviewed by the British Dietetic Association (BDA). It involves eliminating all foods and drinks containing lactose from the diet for two weeks to see if symptoms disappear.

If symptoms do not disappear, then they are unlikely to have LI. If symptoms do substantially reduce then lactose can be slowly re-introduced into the diet see how much can be tolerated. Your customers should not eliminate foods completely and must ensure they eat a range of calcium rich foods.

The elimination diet can be found at www.lactofree.co.uk.

## Managing LI

There is no cure for LI and it can be both a temporary and permanent condition. For those with an intolerance to lactose, a complete diet overhaul is often unnecessary as the symptoms can be easily minimised with a lactose-reduced diet using Lactofree.

Lactofree, the UK's first and only lactose free* dairy range of products - including whole and semi-skimmed milk, hard and soft cheese, flavoured and natural yogurt - allows lactose intolerant individuals to enjoy the full taste and nutritional benefits of cow's milk without the side effects that lactose brings. It can be used in cooking and is suitable for children from the age of one.

Lactofree starts off as regular cow's milk and is filtered to remove nearly all of the lactose. The addition of the lactase enzyme breaks down the remaining lactose, so it can be digested without any unpleasant side effects.

Lactofree is not suitable for people who suffer from galactacemia (a hereditary disease that is caused by the lack of the liver enzyme required to digest lactose).

**References** 1. Are You Missing Something Report, 2006 2. Matthews S et al Systemic lactose intolerance a new perspective of an old problem Postgraduate Medical Journal 2005 81, 167-173

**Visit www.lactofree.co.uk for details on the elimination diet, a list of foods containing lactose and information on how your customers can manage the condition.**

**Useful tips for helping people to learn about their condition and stay well:**

- Always check the labelling on food for lactose or milk derivatives
- Check the labelling on tablets and inform the pharmacist dispensing the medicine of the condition
- In the early stages of diagnosis, keep a food diary to establish which foods cause symptoms
- Carry some lactase enzyme tablets or drops for when lactose avoidance is not possible
- Use Lactofree products

**Lactofree can be found in all major supermarkets nationwide**

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AAH boss Mark James tells **Max Gosney** why wholesalers should not be the fall guys for the stock problems plaguing UK pharmacies

# Making his mark

Out of stock, product under manufacturer quota, limited stock from supplier. The explanations from wholesalers on why they can't supply some branded drugs grow longer by the day.

"I totally understand our pharmacists' frustration," says Mark James, group managing director at AAH. But, blaming wholesalers is plain wrong, he stresses. "To suggest we would not want to sell the product when we have it is ridiculous. If we have it, we will supply it."

And wholesalers more often than not do have it, he says. "Out of 6,000 products on any individual day we would be looking at 100 products out of stock. That's not that different from five years ago." Despite rumblings over worsening medicine shortages, stock levels on branded drugs have been pretty consistent since the mid-90s, Mr James says. "If you go back to 1996 you would see a service level of 98 per cent on branded. It dipped by a few per cent that year and for many years we've not been above 96 per cent."

What has marked out recent years has been the growing length of time products stay unavailable, Mr James explains. All wholesalers receive set supply limits from manufacturers on many products, the AAH boss says. Once those limits have been reached no further stock is made available until the next agreed delivery date, he adds.

Manufacturers are increasingly reluctant to release extra stock as the UK economy weakens. A frail pound against the euro is fuelling a boom in parallel exporting of medicines across the channel. The current situation is akin to a stalemate between big pharma and contractors. On one side pharmacists complain that they can't get hold of vital NHS drugs. On the other manufacturers refuse to increase stock levels because, they claim, some contractors will simply sell it on to the continent at a profit.

Parallel exporting, which remains totally legal, has been lambasted by PSNC as sullying the good name of pharmacy. Yet, Mr James takes a more impartial view. "You can look at this and say we're in the EU, this is a single market; therefore there should be no restrictions on product," he says. "The other view is that it's all very well where pricing can be determined by the free market. But in Europe, there is a series of individual markets each setting the price."

The upshot is that manufacturers lose out as products are traded from low cost countries for resale in more expensive lands. This helps keeps medicines bills down, but you can understand why manufacturers, who have spent large sums on developing new drugs, get frustrated, says Mr James.

Mr James's recognition of big pharma's viewpoint is revealing. Distribution deals mean wholesalers are now operating a business model where drugs firms are as much their customers as the local pharmacy.

He says: "We have to be much more balanced in our view between pharmacists and the manufacturers. It would be nice to be able to stand up and have a strong opinion, but it would be a fairly career-limiting approach."

An astute sense of judgement is perhaps one of the attributes that has helped Mr James rise to the top at AAH. He joined the company as operations director in 1997 and progressed to group managing director in February last year.

He can look back on a successful first year in charge. The wholesaler featured in all five manufacturer-led deals in 2008 and in one of three to hit the market this year. It's been a challenging task, Mr James reflects. "Competition has got more intense. Nearly every distribution deal results in less money for the wholesaler. Everyone's feeling the pressure."

Maintaining high quality service to pharmacies will be key to success as conditions grow tougher says the AAH boss. "We are putting more effort into supply issues than we've ever done. We've spent nine months completely reviewing IT systems." But attention will also be drawn to the next wave of manufacturer supply deals, Mr James predicts.

Any drugs firm that believes its product cannot be substituted has a potential distribution deal in the pipeline, he says. The sector is simply reaping what was sewn with the first distribution deal three years ago. "What we're facing now is a consequence of the Pfizer deal. You have to take a stance that means you go out of business or you play the game."

AAH may have been a spectator for that original Pfizer scheme, but there's no doubt the wholesaler wants to be in the game for every deal that comes in its wake.

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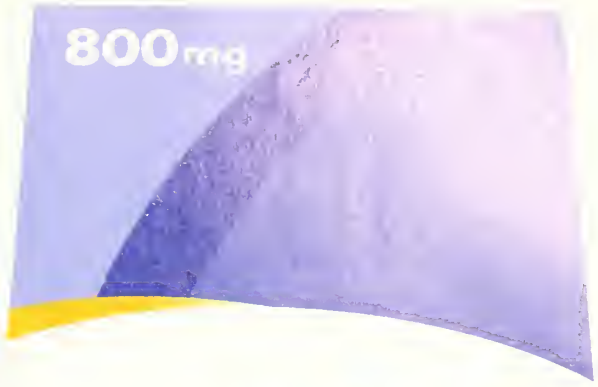
# Strength

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1. Asacol 800mg MR tablets Summary of [illegible] 2007

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**Xrayser** haveyoursay@cmpmedica.com

# Criminal decision sets a frightening precedent

**Every pharmacist reading** Elizabeth Lee's story (C+D, April 11, p6) will think, "that could be me". I did, and it chilled me to the bone. This issue will unite the profession in empathy for Mrs Lee and concern for our future. Its implications should not be underestimated.

No amount of SOPs, rest breaks, support staff or safety procedures can ever completely rule human error out of dispensing. It's just as easy to mistakenly label a 30g tube of Fucidin as the 15g size as it is to label a pack of propranolol as prednisolone. The first type of error serves as a reminder to re-assess procedures, while the second is potentially catastrophic.

We are all familiar with that sick feeling in the pit of the stomach that accompanies the realisation that you've made a dispensing error.

Actually harming a patient through an error is a test of the individual pharmacist's character and resolve as to how, or even if, they continue to practise. But to be branded a criminal, or even sent to prison, on top of all that will ruin more than the pharmacist's career.

There can be no other profession where a one-off mistake can lead directly to a criminal conviction, however serious the implications. An airline pilot, for example, is not sent to prison for an individual uncomplicated human error, however many passengers may be on board.

It is a tribute to the integrity and value of community pharmacy dispensing that, despite dispensing more than 2.5 million items every day in England alone, terrible mistakes like this rarely happen.

But this is bad news for patient safety, as the NPSA will find it virtually impossible to encourage pharmacists to report any mistakes they make. Nobody in their right mind will volunteer to criminalise themselves in this way, even though we are all, by definition, criminals for making errors.

An ever-increasing workload with no compensatory adjustments will inevitably lead to more mistakes. The RPSGB's Workplace Pressure campaign will hopefully begin to address the appalling conditions under which some of us work. Minimum standards must be set for working hours, workload and support systems.

Goodwill, already in short supply, could evaporate completely if something is not done. Employees and locums may not be prepared to accept the risks associated with working in pharmacies with a heavy dispensing business, inadequate support, or long opening hours.

> "The NPSA will find it virtually impossible to encourage pharmacists to report any mistakes they make. Nobody in their right mind will volunteer to criminalise themselves in this way"

And we must all start to question our willingness to accept the increasing responsibility the DH wants us to bear, with legislation such as the responsible pharmacist. Who wants to be responsible for errors made while they are absent from the pharmacy, or even those made by an ACT while they are present?

The RP legislation will inevitably lead to more cost-cutting measures, making the situation worse. Where will it all end?

Do you agree with Xrayser?
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**Letter of the Law** David Reissner

# There's no level playing field when it comes to duty of care

**In my last column, I explained** how a pharmacy contractor who was owed money by a PCT could sue. The same does not apply when the PCT is negligent in the way it administers the pharmacy contract. For example, I see many cases in which PCTs fail to notify existing pharmacy owners of applications for new pharmacies that would affect their businesses. In one recent case, a PCT had long ago granted a pharmacy application in a rural area but took years to get round to telling local dispensing doctors they had to cease dispensing for patients living within a mile of the new pharmacy.

To recover damages for negligence, a claimant must show not only that a defendant has been negligent and caused loss, but that the defendant also owed the claimant a duty of care. People use the expression 'duty of care' rather freely these days. However, the courts take a more restrictive approach and tend to be protective of public bodies that exercise statutory duties.

In a recent case decided by the House of Lords, the owners of a nursing home had their business destroyed when Trent Strategic Health Authority took unjustified action to cancel the home's registration without prior notice. As a result, 33 elderly and infirm people who lived at the home were immediately removed. The owners won an appeal, but it was too late to save their business. The Law Lords decided that if victims of the Health Authority's negligence could sue for damages, it would mean that Health Authorities might be inhibited from exercising their duties to protect patients in other cases where intervention might be justified.

The absence of a duty of care gives PCTs no incentive to ensure their actions meet appropriate standards. PCTs now have significant powers to deal with underperformance by healthcare professionals. What is needed is a suitable body that can deal swiftly with underperformance by PCTs, and with the power to award compensation in appropriate cases.

The NHS Bill currently going through Parliament will require NHS bodies and providers of services to have regard to an NHS Constitution that sets out certain core principles and patients' rights. The Constitution will give patients the right to have complaints properly investigated and dealt with efficiently. It says a lot about the rights of NHS employees, but nothing yet about the rights of others who provide NHS services.

A pledge to deal fairly and efficiently with the grievances of all who provide NHS services would be appropriate and welcome.

**David Reissner is a solicitor and head of healthcare at Charles Russell LLP, where he is a partner**

Your Guide To...

# New supply arrangements for incontinence and stoma products

**Fiona Salvage** spells out what the new stoma arrangements mean for pharmacists

## What's happened?

The Department of Health has finally finished its review of the reimbursement and supply of stoma and incontinence products listed in Part IX of the Drug Tariff. The review started back in 2006 and has been fraught with difficulties because of the lack of parity between what pharmacy contractors and dispensing appliance contractors (DACs) could offer with regards to delivery and extras such as wipes and disposal bags.

## Who does this affect?

All pharmacy contractors in England and all dispensing appliance contractors supplying to patients in England.

## When does it come into affect?

Not until April 1, 2010. There must be amendments to the National Health Service (Pharmaceutical Services) Regulations 2005 before the service can be launched. PSNC expects provision will be made in the regulations to give pharmacy contractors six months to comply with the new arrangements. So, if the amended regulations start on April 1, 2010, contractors would have until October 1, 2010, to comply.

The Advanced Services will come under Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2005. The Department of Health intends the amended Regulations to be laid before Parliament at least six months before they come into force on April 1, 2010.

## What's changed?

Services are split between essential services and the introduction of two new advanced services.

**Essential services**

1 Home delivery service and supply of wipes and disposal bags
2 Provide appropriate advice
3 Dispensing referral
4 Repeat dispensing service
5 Urgent supply without a prescription.

PRESCRIPTIONS

> "The DH intends the amended regulations to be laid before Parliament at least six months before they come into force"

**Advanced services**

1. Stoma appliance customisation
2. Appliance use reviews (AURs).

DACs need to operate within a similar clinical governance framework to pharmacy contractors. Their previous "on-cost" arrangement will be replaced with fees and allowances laid out in the Drug Tariff (DT).

## What do the changes mean?

**Essential services**

1. Home delivery service and supply of wipes and disposal bags. There will be a requirement for all qualifying items in Parts IXA, IXB and IXC in the Drug Tariff to be available through home delivery. The patient can choose to collect it or have it delivered to their home. A reasonable supply of wipes and disposal bags also needs to be supplied.
2. Provide appropriate advice. This is advice for the patient on using, storing and disposing of the appliance appropriately. Contractors must also ensure the patient can, if they wish, consult someone for expert advice about the appliance being dispensed. Patients supplied via repeat dispensing must also be provided with advice on only ordering those items they actually need.
3. Dispensing referral. If a pharmacy cannot dispense the prescribed item or cannot customise the appliance, there will be a requirement, with the patient's consent, to refer the prescription to another pharmacy or

## What's the funding for this?

| Service | Fee Level |
|---|---|
| Dispensing | 90p (as now) |
| Additional dispensing service (home delivery) | £3.40 per qualifying item, other than intermittent self-catheters (ISC) for which £9.30 will be paid per ISC dispensed |
| Dispensing of appliances measured and fitted | £2.60 per item based on endorsement of measured and fitted. Includes belts and girdles |
| Expensive prescription fee | 2 per cent of net ingredient cost on all prescriptions over £100 (as now) |
| Stoma customisation | £4.32 for every qualifying Part IXC prescription item dispensed (regardless of whether customisation was required) |
| Appliance use reviews | £27 per AUR held on pharmacy premises. £54 per AUR conducted at user's home. More than one AUR conducted in same place within 24-hour period is £54 for first AUR and £27 for each subsequent AUR. The total number of AURs a contractor can claim for is limited to one per every 35 Part IXA (qualifying items), Part IXB and Part IXC prescription items dispensed in a year (April to March). |

dispensing appliance contractor. If the patient doesn't consent, contact details for two other contractors who may be able to dispense the item or service will have to be provided, where the details are known. Pharmacy contractors are not allowed to receive or accept any gifts or rewards for making any referrals of this nature.
4. The repeat dispensing service is already provided by pharmacy contractors.
5. Urgent supply without a prescription. In an urgent case, the pharmacy contractor or DAC may supply an appliance, if asked by a prescriber to do so, as long as the prescriber gives the pharmacist or DAC a non-electronic prescription form or non-electronic repeatable prescription for the appliance within 72 hours. Or the prescriber must transmit to the ETP service an electronic prescription within 72 hours.

**Advanced services**

1. Stoma appliance customisation. This is modifying multiple identical parts to the same specification for use with a stoma appliance.
2. Appliance use reviews (AURs). Pharmacy contractors can choose to provide AURs. Before providing them they must make a one-off declaration of their intention to provide either or both advanced services to the NHS BSA (Business Services Authority – Prescription Services). The form will be available on the NHS BSA's website nearer the time.

Contractors will need to contact their PCT with their intention to provide either or both of the advanced services. They will be in relation to Part IXA (qualifying items), Part IXB or Part IXC prescription items. The AUR can be carried out either by a pharmacist or a specialist nurse working on behalf of the pharmacy contractor who dispensed the appliance. AURs can be conducted either at the pharmacy or at the user's home.

If the AUR is done at the pharmacy it is similar to an MUR in that it must be conducted in a clearly designated place for confidential consultation that is distinct from the general public area. The area needs to be somewhere both user and pharmacist or specialist nurse can sit down together and talk at normal speaking volumes without being overheard.

## What's a qualifying item?

Qualifying items for home delivery are:
- Items in Part IXB and IXC of the Drug Tariff.
- The following items in Part IXA of the DT – catheter, laryngectomy and tracheostomy, catheter accessories, catheter maintenance solutions, anal irrigation system, vacuum pumps and constrictor rings for erectile dysfunction, and wound drainage pouches.

Qualifying items for customisation are:
- Part IXC items – one-piece closed bags (under "colostomy bags" in the DT), drainable bags (under "ileostomy bags") and bags with tap (under "urostomy bags"), items under "two-piece ostomy system" and "flanges", skin protectors and stoma caps.

## What is the impact on existing services?

As home delivery is intended to be an essential service, the existing direction to PCTs to commission these services as a local enhanced service will be revoked six months after the new arrangements come into force. PCTs will decommission local enhanced service arrangements with contractors within six months of the new regulations coming into effect.

## What else will change?

There will be a 2 per cent reduction on the reimbursement prices of Drug Tariff Part IXA catheters, Part IXB incontinence appliances and Part IXC stoma appliances. The new prices will come into effect on April 1, 2010, and will be in the April 2010 Drug Tariff.

Six months after the new arrangements come into effect, a reimbursement price increase mechanism will be introduced. This is because the previous price increase mechanism was suspended in April 2006.

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C+D Clinical

# Understanding prostate cancer

The first of two articles explains the pathology and diagnosis of this common cause of death

## 60-second summary

**What are the chances of developing prostate cancer?**
It is the second leading cause of cancer-related death in UK men and the lifetime risk of having it diagnosed is one in 10, although many more have 'latent' disease.
**What are the main risk factors?**
Age above 50 years, family history, African race, high dietary intake of fat and dairy products; other factors have been suggested but the evidence is inconclusive.
**If the best outcomes arise from early detection, why aren't all men screened?**
The natural history of the disease is poorly understood and diagnostic tests have their shortcomings. Even the 'gold standard' diagnostic tool – transrectal prostate biopsy – can sometimes be inconclusive.

**Naomi Sharma**

Prostate cancer is the most common cancer affecting men in the UK, with over 34,000 cases diagnosed in 2005.[1] It is the second leading cause of cancer-related death in men in the UK and the lifetime risk of developing prostate cancer is around one in 10. However, post-mortem studies in men who have died of other causes show the incidence of prostate cancer is still higher in older men, and it is clear many men have 'latent' prostate cancer.

Risk factors include age above 50 years (see figure 1, online at www.chemistanddruggist.co.uk/update), a history of prostate cancer in a first-degree relative (father or brother) under age 55, African

CPD

This article (Module 1473) can help in the following CPD competencies:
**G1a, C1f, C2e**
See http://tinyurl.com/68ox7b

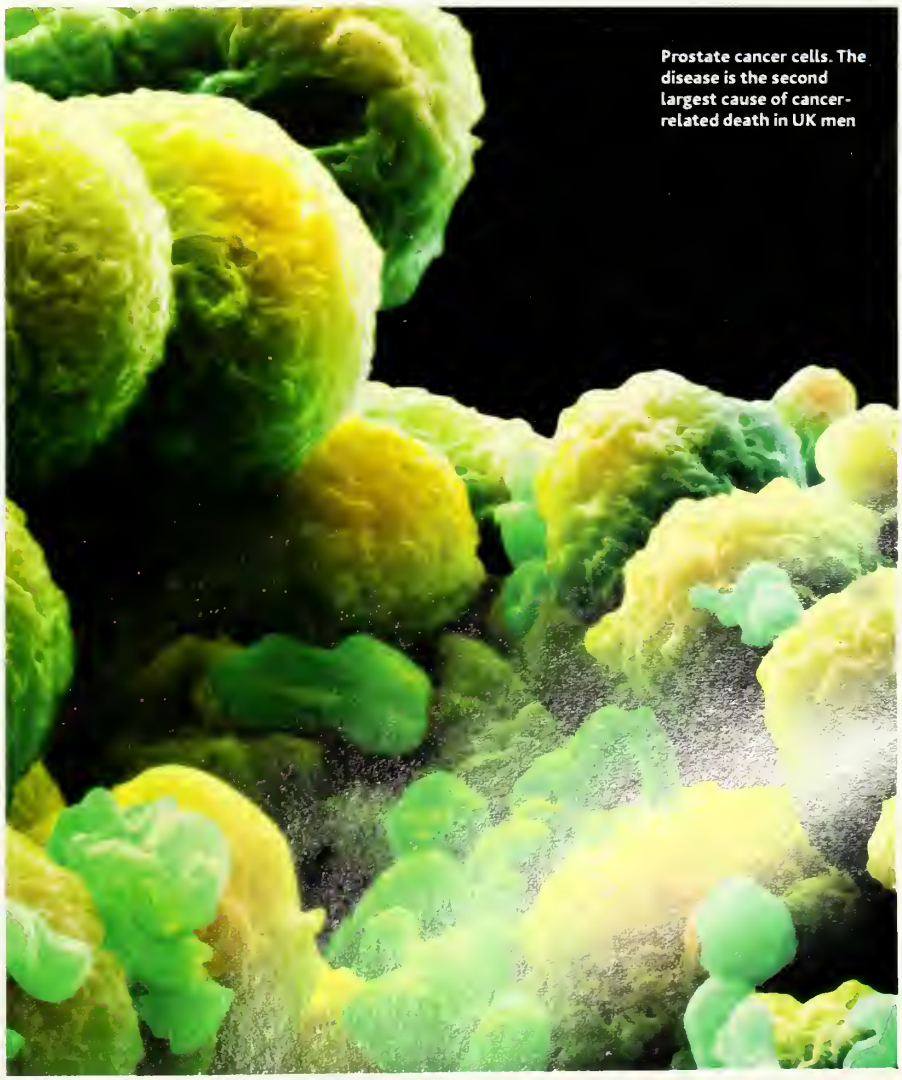
Your Continuing Professional Development CPD

## Reflect

What are the risk factors for prostate cancer? How accurate is a prostate specific antigen test? What complications may follow a transrectal prostate biopsy?

## Plan

This article describes the signs, symptoms and risk factors of prostate cancer. It includes information about the diagnostic tests and their results and accuracy.



Prostate cancer cells. The disease is the second largest cause of cancer-related death in UK men

Photo: Science Photo Library

NAPP PHARMACEUTICALS

# *BuTrans*®: a moderate analgesic for moderate OA pain

NICE guidance recommends the use of an opioid when pain relief with paracetamol and topical NSAIDs have proved inadequate[1]

## 7 days continuous relief from OA pain

***BuTrans***® patches – for the treatment of moderate non-malignant chronic pain.

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Buprenorphine Matrix Patch 5µg/h, 10µg/h, 20µg/h

**Continuous relief from OA pain 24/7**

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**Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Napp Pharmaceuticals Limited on 01223 424444.**

For medical information enquiries, please contact medicalinformationuk@napp.co.uk

Reference
1. NICE clinical guideline 59. The care and management of osteoarthritis in adults, February 2008. Available at: http://www.nice.org.uk/nicemedia/pdf/CG59NICEguideline.pdf

Date of preparation: March 2009

UK/BU-09031

race, and a high dietary intake of fat and dairy products. Other risk factors including vasectomy and sexual activity have been suggested but none have conclusive evidence to support them.

As with other cancers, there is considerable interest in understanding the mechanisms of prostate cancer initiation and progression, and research efforts have increased tremendously over recent years.

The detected incidence of prostate cancer has been increasing, probably because of increased prostate specific antigen (PSA) testing and the use of more extensive biopsy protocols. In contrast, mortality has reduced slightly over the past 10 years (see figure 2 online at www.chemistanddruggist.co.uk/update), which may be due to PSA testing and initiation of early treatment. Despite the importance of this disease, there is significant controversy regarding its diagnosis and management.

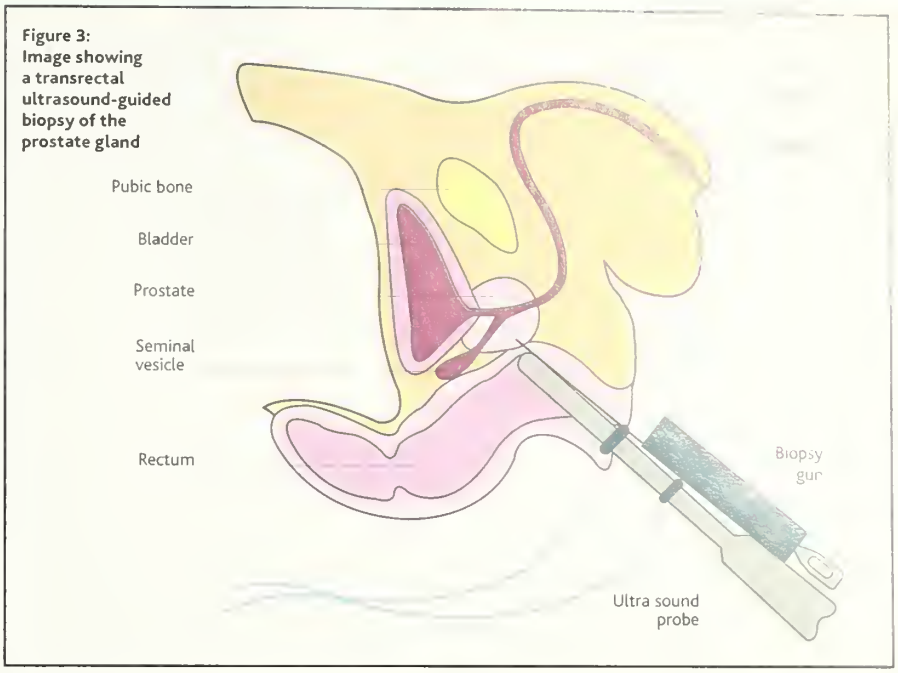



**Figure 3: Image showing a transrectal ultrasound-guided biopsy of the prostate gland**

## Symptoms and signs

Most prostate cancers are slow-growing and cause few, if any, symptoms. These can include lower urinary tract symptoms, such as frequency of urination, difficulty emptying the bladder, and burning or stinging when passing urine; blood in the urine or semen; and discomfort in the genital region. More rarely, patients can present with symptoms of advanced disease, such as weight loss, leg swelling from obstruction of lymphatic drainage, bone pain, renal failure from ureteric obstruction and jaundice from liver metastasis.

In most patients the examination is entirely normal. This should include a digital rectal examination (DRE), which gives information on the presence of malignancy, the extent of any spread to adjacent organs and an estimation of the size of the prostate gland. The presence of a nodule, or a firm and/or irregular-feeling lobe, should prompt further investigation, and around 30 per cent of patients will have prostate cancer.

The importance of a DRE should not be underestimated: an abnormal DRE in the presence of a normal PSA carries a 30 per cent chance of predicting prostate cancer. The prostate examination will allow the clinician to identify the 'clinical stage' of the cancer (see table 1). This is important in planning treatments and appropriately counselling the patient.

More rarely there may be signs of advanced disease, such as oedema of the legs, a palpable enlarged liver, cachexia and jaundice.

## Diagnosis

As with many other cancers, the best outcomes arise from early detection. At present, there is no screening for prostate cancer in the UK. The World Health Organization has issued criteria that proposed screening programmes must fulfil, and prostate cancer does not yet achieve these.[2] For example, the natural history of the disease is poorly understood, and there is not yet a suitable screening test. In the future, it may be that improved tests will be available and more known about the natural history and best treatment of prostate cancer. With this information, a screening programme could be launched.

Besides the DRE, several other diagnostic tests exist, including serum and urine tests. The commonly used serum test is a measure of PSA (prostate specific antigen). PSA is a glycoprotein produced by the prostatic epithelial cells. It is elevated in patients with prostate cancer, but also in older men, patients with urinary tract infection, patients with benign prostatic hypertrophy, and patients who have undergone recent urinary instrumentation such as catheter insertion. Also many men with a 'normal' PSA (less than 3ng/ml) have prostate cancer if they are biopsied.

This blood test is widely known to both health professionals and patients, but has practical limitations. A common way of assessing the utility of a test is to know the sensitivity (the proportion of diseased subjects who test positive, ie the number of true positives) and the specificity (the proportion of unaffected subjects who test negative, ie the number of true negatives). Clearly, the best test is one that combines a high sensitivity with a high specificity.

Traditionally, a PSA value of 4ng/ml was used as a cut-off level above which patients were offered a biopsy. Using a value of 4.1ng/ml, the PSA test has a sensitivity of 20 per cent (so 80 per cent of men with prostate cancer would be missed and not offered a biopsy) but a specificity of 94 per cent (so 6 per cent of people without the disease would have an unnecessary biopsy).

There is obviously a trade-off between a higher sensitivity and a lower specificity, and, for this reason, other tools to look at PSA levels are used, such as age-specific thresholds, PSA velocity, PSA doubling time, the ratio of 'free' and 'complexed' PSA, and a combination of all of these. There remains no clear guidance on which of these models is best.

Another test, although not yet available within the NHS, is the urine test for PCA3

**TABLE 1: RECTAL EXAMINATION FINDINGS FOR CLINICAL STAGES OF PROSTATE CANCER**

| Clinical tumour stage | DRE findings |
|---|---|
| T1c | Cancer non-palpable |
| T2a | Palpable tumour; <half of one lobe |
| T2b | Palpable tumour; >half of one lobe |
| T2c | Palpable tumour; in both lobes |
| T3a | Palpable tumour; advanced into fat surrounding prostate |
| T3b | Palpable tumour; advanced into seminal vesicles |
| T4a | Palpable tumour; advanced into adjacent structures, fixed |
| T4b | Palpable tumour; advanced into pelvic side-wall, fixed |

(prostate cancer gene 3). This marker is overexpressed in the urine of men with prostate cancer, and more significantly in those men with advanced and/or aggressive disease.[3] At present, it is being used in predicting the chance of a positive repeat biopsy, after a patient with a raised PSA has had a negative biopsy (ie no cancer identified on histology).

The 'gold standard' for diagnosis is transrectal prostate biopsy, with ultrasound guidance (see figure 3 on p19). It is usually performed in the outpatient clinic and under local anaesthetic and antibiotic cover. The number of biopsies taken depends on the operator's preference, but commonly ranges from six to 10.

Complications include urinary tract infection, bleeding (visible in the urine and/or stool) and, less commonly, sepsis. The prostate biopsy can also be performed via a perineal approach if more biopsy cores are required, or if the prostate cannot be accessed via the rectum, eg in the case of previous rectal surgery, although this is done under a general anaesthetic.

If cancer cells are found in the biopsy, the Gleason grade indicates at what stage of development the cells are. Each number corresponds to a histological pattern of decreasing differentiation from one to five, where five is the least like a normal prostate cell, ie the least well differentiated and therefore carrying the worst prognosis. The Gleason score represents the most prevalent and the second most prevalent pattern, eg Gleason grade 3+4=7.

While the biopsy is the 'gold standard' diagnostic tool, the results can sometimes be inconclusive, revealing abnormal pathology but not cancer (eg prostatic intra-epithelial neoplasia, PIN). In these cases, the biopsy should be repeated, as PIN can be associated with cancer in 20 to 30 per cent of patients.[4]

To help calculate the risk of the cancer being confined to the prostate gland, and to know the likely outcomes of treatments, urologists and patients can use nomograms. One example is the Memorial Sloan Kettering Hospital nomogram (available at www.mskcc.org/mskcc/html/10088.cfm).

Once a diagnosis of prostate cancer is made, the patient undergoes a variety of staging investigations to assess the extent of the disease, using the TNM classification (tumour, nodes and metastases). Knowing the stage of the disease is important to identify treatment options and to counsel the patient regarding prognosis. For example, a patient with low volume Gleason Grade 6 disease and a low PSA, and no evidence of tumour spread (localised disease) has a disease-specific survival of 90 per cent at 10 years.

Nodal disease (in lymph nodes) is assessed using CT or MRI imaging, and metastases are assessed most commonly by MRI or an isotope bone scan. Usual practice is to assess skeletal metastases with a bone scan if the PSA is greater than 10ng/ml, and not to look for distant metastases if the PSA is less than 10ng/ml, as the risk of having metastases is small. Nodes are either not present (N0) or loco-regional. Depending on their size, they are classified as N1 (less than 1cm), N2 (a lymph node between 1cm and 5cm, or more than one lymph node), or N3 (greater than 5cm). Metastases are either not present (M0), found on a lymph node outside of the pelvis (M1a), a metastasis in bone (M1b) or in another organ, such as the liver (M1c).

A full version of this article, Module 1473, is available on C+D's website at www.chemistanddruggist.co.uk/update. It includes the references and figures 1 and 2.

Naomi Sharma is a urology academic registrar at Addenbrooke's Hospital, Cambridge.

## Your Continuing Professional Development

CPD

### Act

- Read the additional information about risk factors for prostate cancer on the Cancer Research UK web site (http://tinyurl.com/brjyux).
- Learn more about the prostate specific antigen test from the Patient UK web site (www.patient.co.uk/showdoc/40025954).
- Find out how transrectal ultrasound-guided biopsy is carried out, on the Prostate Cancer Charity website (http://tinyurl.com/bexvrv), which also explains more about Gleason Grading (http://tinyurl.com/c55tgf).
- Familiarise yourself with the Memorial Sloan Kettering Hospital nomogram mentioned in the article (www.mskcc.org/mskcc/html/10088.cfm). Could it be of use when counselling patients about their prostate cancer?
- Think about advice you could give to a patient asking about symptoms that may indicate prostate cancer. What questions would you ask?
- Make a note to read next week's Update on treatments for prostate cancer.

### Reflect

Are you now familiar with the signs and symptoms of prostate cancer? Do you know who is most at risk? Are you confident in your knowledge of the tests and procedures that are used to diagnose this disease?


**PRODUCT INFORMATION FOR NUROFEN PLUS** Nurofen Plus: Tablets containing 200mg ibuprofen, 12.8mg Codeine Phosphate. **Indications:** For the relief of pain in such conditions as: rheumatic and muscular pain, backache, neuralgia, migraine, headache, dental pain, dysmenorrhoea, feverishness, symptoms of colds and influenza. **Dosage and Administration:** Adults and Children over 12 years: one or two tablets every four to six hours. Do not take more than 6 tablets in 24 hours. Do not take for more than 3 days continuously without medical review. Not for use by children under 12 years of age. Elderly: No special dosage modifications are required unless renal or hepatic function is impaired, in which case dosage should be assessed individually. The minimum effective dose should be used for the shortest time necessary to relieve symptoms. The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 3 days. **Contraindications:** Hypersensitivity to ibuprofen or any of the constituents in the product. Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs. Active or previous peptic ulcer. History of upper gastrointestinal bleeding or perforation, related to previous NSAIDs therapy. Use with concomitant NSAIDs including COX-2 inhibitors. Severe hepatic failure, renal failure or heart failure. Last trimester of pregnancy. Hypersensitivity to codeine, respiratory depression, chronic constipation. Severe heart failure. **Precautions and Warnings:** Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease. Use minimum effective dose for the shortest possible duration. The elderly are at increased risk of the serious consequences of adverse reactions. Use with caution in hypotension and/or hypothyroidism and in patients with raised intracranial pressure or head injury. Systemic lupus erythematosus and mixed connective tissue disease – increased risk of aseptic meningitis. Chronic inflammatory intestinal disease (ulcerative colitis, Crohn's disease) may be exacerbated. Hypertension and/or cardiac impairment as renal function may deteriorate and/or fluid retention occur. Long-term (particularly at high doses 2,400mg daily) ibuprofen treatment may be associated with increased risk of arterial thrombotic events (Myocardial infarction or stroke). Renal impairment. Hepatic dysfunction. NSAIDs may impair female fertility by a reversible effect on ovulation. GI bleeding, ulceration or perforation which can be fatal, has been reported with all NSAIDs with or without warning symptoms or a previous history of serious GI events (withdraw treatment). Caution with concomitant oral corticosteroids or anticoagulants such as warfarin or anti-platelet agents such as aspirin. Side effects: Hypersensitivity reactions including (a) Non-specific allergic reactions and anaphylaxis. (b) Respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm, dyspnoea. (c) Various skin reactions, e.g. pruritus, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme). Side effects to codeine [illegible] cough [illegible] prolonged [illegible] symptoms of [illegible] treatment is then [illegible] headaches can make them [illegible] gastrointestinal adverse events, see the [illegible] characteristics. **Product Licence Number:** P 00324/0082. Licence Holder: Crookes Healthcare Limited, [illegible] NG2 3AA. **Legal Category:** P. **Price:** MRRP from £2.77 for 12 tablets. **Date:** June 2008.

Information about adverse event reporting can be found at www.yellowcard.gov.uk
Adverse events should also be reported to the Medical Information Unit, Reckitt Benckiser, Hull.
Telephone (0500 455 456).

Always read the label. Only available in pharmacies.

# Everybody hurts

Confused about the options for OTC analgesia? **Chris Chapman** explores the pain body map and its treatment

There's a point in the classic movie The Princess Bride when a kidnapped princess turns to face her masked rescuer. Unaware he's really her presumed-dead true love, she laments the loss of her sweetheart. The hero responds with his best Errol Flynn laugh.

"You mock my pain," the princess complains.

The dashing rescuer casts her a steely look. "Life is pain, highness," he retorts. "Anybody who says differently is selling something."

If the Hollywood fairytale is right, it's no wonder analgesics is one of the largest categories of OTC medicines available. With such a dizzying array of choices, it's easy to get lost in the maze of potential drugs when advising patients on the best treatment available.

## Associated advice

While analgesics are some of the most common medicines sold in pharmacies, counselling is still important. Many of the conditions requiring OTC analgesia can be eased by alternative methods, which may mean more potent analgesics do not need to be considered.

Advice should be tailored to the patient and many suggestions are widely known, such as lying in a dark room for patients with headaches, or avoiding triggering factors such as caffeine.

Selecting the right option for the patient can be tricky. However, C+D has trawled through the NHS Clinical Knowledge Summaries (http://cks.library.nhs.uk) to provide you with the best advice possible. See the body map, right, for a rough guide of when to consider each treatment.

## The options

There are five main categories of analgesic available OTC: paracetamol, NSAIDs, opioids, triptans and topical treatments. The treatment of choice depends on the location and the type of pain.

Paracetamol is an analgesic and antipyretic but does not reduce inflammation, and so is less effective for muscular pain. It is contraindicated in patients who are heavy drinkers because these patients may have hepatic impairment.

NSAIDs inhibit cyclo-oxygenase and have analgesic, antipyretic and anti-inflammatory properties.

The most common NSAIDs sold OTC are aspirin and ibuprofen. Naproxen tablets and diclofenac are also available, although the oral tablets are only licensed for specific conditions, such as naproxen for period pain.

> "The treatment of choice depends on the type and location of pain"

Oral NSAIDs can cause side effects such as gastrointestinal bleeding, which makes them unsuitable for older patients and women who are pregnant. Aspirin should be avoided in children under 16 years because of Reye's disease.

The main opioid analgesics available OTC are codeine and dihydrocodeine, which are sold in conjunction with paracetamol. These are the strongest analgesics available but do not have anti-inflammatory properties.

The use of codeine and dihydrocodeine as OTC remedies should be limited, as they may cause addiction. Patients who regularly purchase these drugs may require counselling on the use of their medicines.

Triptans, or $5HT_1$ agonists, are used to treat acute migraine. Currently only sumatriptan is available OTC.

Sumatriptan is indicated for adults with an established pattern of migraine (five or more

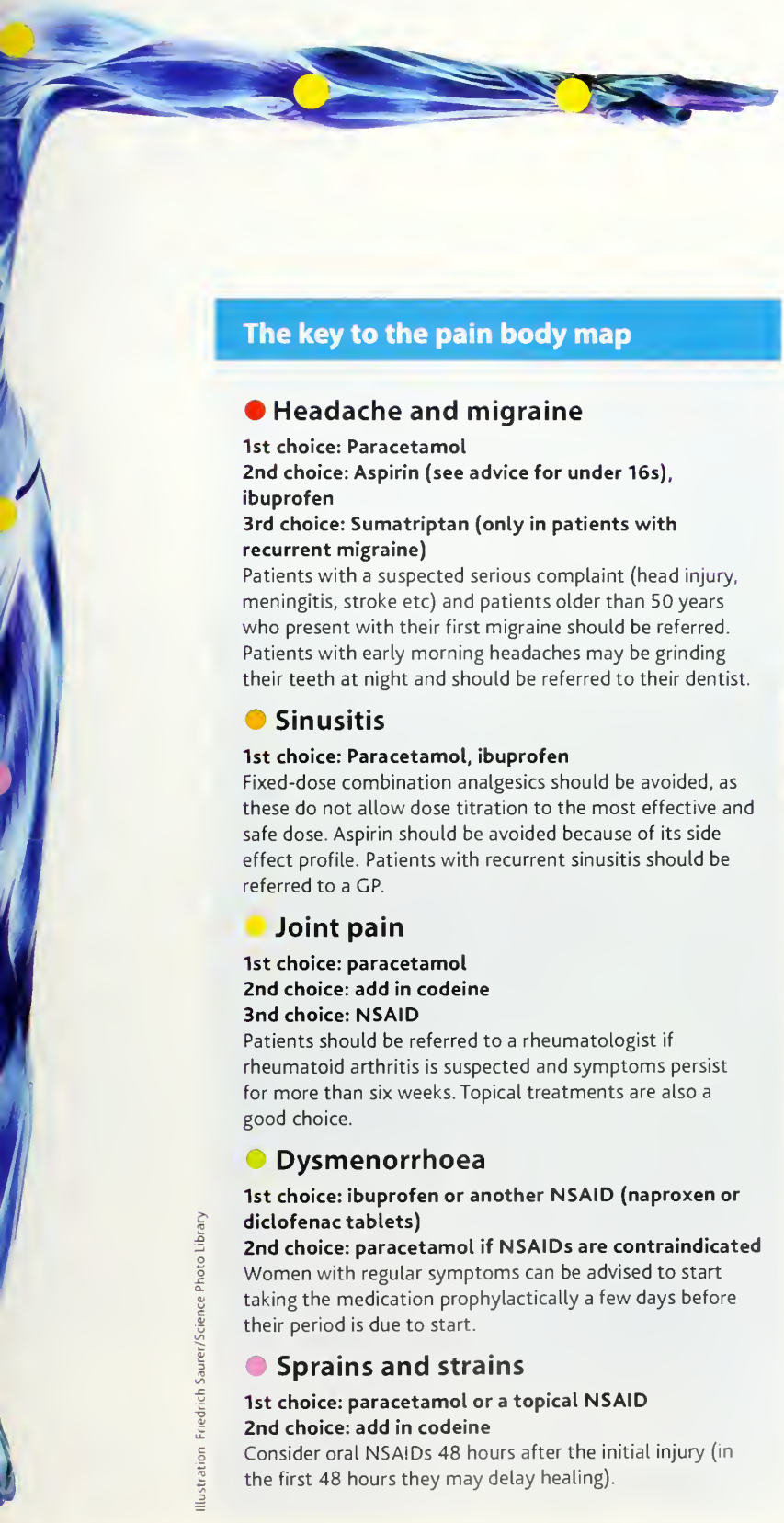


Illustration Friedrich Saurer/Science Photo Library

## The key to the pain body map

### Headache and migraine

**1st choice: Paracetamol**
**2nd choice: Aspirin (see advice for under 16s), ibuprofen**
**3rd choice: Sumatriptan (only in patients with recurrent migraine)**
Patients with a suspected serious complaint (head injury, meningitis, stroke etc) and patients older than 50 years who present with their first migraine should be referred. Patients with early morning headaches may be grinding their teeth at night and should be referred to their dentist.

### Sinusitis

**1st choice: Paracetamol, ibuprofen**
Fixed-dose combination analgesics should be avoided, as these do not allow dose titration to the most effective and safe dose. Aspirin should be avoided because of its side effect profile. Patients with recurrent sinusitis should be referred to a GP.

### Joint pain

**1st choice: paracetamol**
**2nd choice: add in codeine**
**3nd choice: NSAID**
Patients should be referred to a rheumatologist if rheumatoid arthritis is suspected and symptoms persist for more than six weeks. Topical treatments are also a good choice.

### Dysmenorrhoea

**1st choice: ibuprofen or another NSAID (naproxen or diclofenac tablets)**
**2nd choice: paracetamol if NSAIDs are contraindicated**
Women with regular symptoms can be advised to start taking the medication prophylactically a few days before their period is due to start.

### Sprains and strains

**1st choice: paracetamol or a topical NSAID**
**2nd choice: add in codeine**
Consider oral NSAIDs 48 hours after the initial injury (in the first 48 hours they may delay healing).

migraine attacks, with the first attack occurring more than 12 months ago) if oral analgesics are ineffective. It is available OTC as an oral tablet.

A single dose should be taken as soon as possible after onset. If the first dose is not effective, a further dose should not be taken. However, a second dose is appropriate a minimum of two hours later if the first dose is effective but symptoms return.

No more than two doses should be taken in 24 hours. Triptans should not be used prophylactically. Patients who experience four or more attacks per month should be referred.

Finally, there are topical treatments, including sprays and hot and cold patches. These include topical levomenthol, which can be used to relieve tension headaches, and heat rubs for muscular or arthritic pain.

The mechanism of action varies; some topical treatments act as anaesthetics, while others cause localised vasodilation.

These treatments should not be applied to broken skin, and patients should always be advised to wash their hands after application.

Topical agents have the advantage of avoiding the risk of GI side effects.

**For more information see C+D's Update articles and product-specific information at www.chemistanddruggist.co.uk**

# Product news

## New TV ad for Liquifast


Anadin will launch a new TV commercial next month to support its new Liquifast capsules.

The new 10-second ad will join the commercial currently appearing on all channels every other week through 2009.

The Liquifast capsules, which contain ibuprofen, are available as both a GSL 200mg dose and as 400mg P medicine.

**Price:** Anadin LiquiFast Double Strength 400mg, £3.91 for 10, £7.33 for 20; Anadin LiquiFast 200mg, £1.95 for 8, £2.44 for 12, £2.93 for 16

Wyeth Consumer Healthcare, tel: 01628 669011

## Free kit available for Imigran Recovery

A free point of sale kit for Imigran Recovery is now available for pharmacies.

The kit, which includes script bags, posters and shelf barkers designed to support sales of the OTC triptan. Training [illegible] also available online.

In addition, a [illegible] form will also be available for [illegible] intolerant.

**Price:** Imigran Recovery, £7.72 for 2

www.mypharmassist.co.uk


## Cura-Heat sales soar after ad campaign


Sales of Cura-Heat are up 20 per cent following a TV ad campaign throughout the first quarter of 2009, a spokesperson for the manufacturer has said.

The TV campaign, which featured the slogan 'Get on with life', drove sales of the heat packs, which are applied over clothing for back pain, or in a supportive wrap over the knee or wrist joint to treat arthritic pain.

www.kobayashihealthcare.com

## Latest Panadol training module coming soon


A new training module for Panadol Advance will be available soon.

The module, part of the 'What a Relief' series, will include the product, which is designed to disperse in the stomach up to five times faster than ordinary paracetamol.

The module follows a national TV campaign and in-store leaflets.

**Price:** Panadol Advance 500mg, £1.42 for 16, £2.73 for 32

GlaxoSmithKline Consumer, tel: 020 8047 5000

www.mypharmassist.co.uk

## 4head can work in two minutes


Topical levomenthol can work in as quickly as two minutes, a study has found. The study, which investigated the effect of brand 4head in patients with frequent tension-type headaches, showed effective analgesia in up to 95 per cent of patients within half an hour.

The topical headache treatment is available as both a stick and as hydro-gel strips.

**Price:** 4head, £5.95; 4head Quickstrip, £4.99 for eight

Dendron, tel: 01923 229251

## Ibuleve turns 18

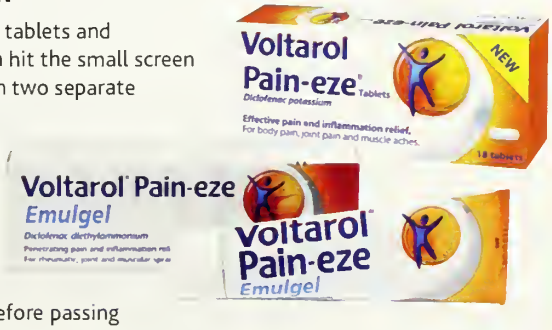

Ibuleve celebrates its 18th birthday this year, with more than 26 million units sold since its launch in 1991.

The topical ibuprofen range, which includes gels, a mousse and a spray, is mostly used by women over 55 years to treat backache, rheumatism and muscular pain.

However, the product is also used by younger users to treat strains caused by sports or lifting children.

**Price:** Ibuleve gel 5%, £4.25 for 30g, £5.95 for 50g, £10.95 for 100g; Ibuleve maximum strength 10%, £5.45 for 30g, £7.45 for 50g

## Voltarol comes to the small screen




Voltarol Pain-Eze tablets and Emulgel will both hit the small screen within a month in two separate campaigns.

The Pain-eze campaign will run throughout April on ITV, C4, five and multichannels, before passing the baton to an Emulgel campaign running throughout May.

**Price:** Voltarol Pain-eze tablets, £5.86 for 18

Novartis Consumer Health, tel: 01403 210211

## Transvasin and Lloyds soothe credit crunch worries


Transvasin and Lloyds Cream could provide a cheap alternative for the five million patients in the UK with back or arthritic pain, the product manager has claimed.

Thornton & Ross brand product manager Ed Round said: "Transvasin and Lloyds Cream can be up to 50 per cent cheaper than some topical analgesics, without any compromise on efficacy."

**Price:** Transvasin Heat Rub, £2.01 for 40g, £3.61 for 80g; Transvasin Heat Spray, £3.08 for 125ml; Lloyds Cream, £2.10 for 30g, £4.20 for 100g

Thornton & Ross, tel: 01484 842217

The evidence for pharmacy's role in public health services is complex. Gavin Atkin reports

# Weight of evidence

There are libraries of good research to support pharmacy interventions in several key areas of public health – but there are also important gaps that urgently need to be filled.

So says a heavyweight report co-written by two professors of pharmacy practice, Professor Claire Anderson of the University of Nottingham and Professor Alison Blenkinsopp of Keele University, together with Miriam Armstrong, chief executive of Pharmacy Health Link, a charity that seeks to promote pharmacy's contribution to public health.

Published by PHLink, The Contribution of Community Pharmacy to Improving the Public's Health: Summary Report reviews the available evidence from 196 studies and reviews with English language abstracts from various countries published between 1990 and 2007.

The selected papers include only interventions with a public health component – for example, studies with an intervention that involved only medicines (for example, a medicines use review) were not reviewed.

It's no great surprise to find the best evidence for pharmacy intervention turned out to be in the areas of smoking cessation, diabetes, emergency hormonal contraception and immunisation against flu. However, Professors Anderson and Blenkinsopp agreed that more results are needed to clarify pharmacy's potential contribution to weight management and cardiovascular disease risk reduction, and there are very few studies in oral health, skin cancer, asthma and head lice.

In the area of smoking cessation, some 36 papers reveal that community pharmacy-based stop smoking services were cost effective, that training for both pharmacists and pharmacy staff is important to success, and that trained pharmacists offering one-to-one treatment services could achieve abstinence levels similar to those achieved by primary care nurses.

They also found involving staff can help in delivering brief advice and recording smoking status.

There was strong evidence that diabetes and cardiovascular screening were effective in identifying people with either diabetes or risk factors for the disease, and that community pharmacy-based diabetes monitoring and information merited further investigation.

In the area of immunisations, pharmacy has been effective in identifying at-risk patients who require flu immunisation. Pharmacist interventions produced significant results in reducing blood lipids and in identifying patients with hypertension but, while there was some suggestion that pharmacy-based services could offer potential benefits in reducing osteoporosis risk and in weight management, both required much more investigation.

The evidence was still weaker in other areas, though, with just three studies of interventions in oral health and skin cancer and just one each in asthma and head lice.

What should we conclude from these results? Professor Blenkinsopp sees two obvious next steps. "Developing services in the areas where we have good evidence is one of the things we'd like people to do," she said. "But a really big thing is that we'd like people to become involved in more UK-based studies. Areas such as weight management appear to be promising from foreign research, but we need more evidence and we need more UK pharmacists to become engaged."

"In some areas we've been brilliant," she says. "We're a world leader in researching in drug misuse and emergency hormonal contraception. But in other areas there is still a contribution to be made and we urgently need data.

"For example, in the area of cardiovascular risk we know that interventions to reduce risk are acceptable to the public, but we know little about what happens when the intervention ceases."

"Also, osteoporosis and falls are areas where we have done great work," she says, "but it has not been evaluated in a way that would provide evidence. So we're looking for community pharmacists to contribute and there have been some good examples where community pharmacists have been involved from the earliest stages of design on through the process to publication."

From her perspective as a successful academic Professor Blenkinsopp might be expected to be especially interested in research but she's also aware of the practical difficulties.

"Pharmacies are businesses too and the NHS now recognises this in its research funding. Its Research for Patient Benefit (RfPB) programme asks researchers to identify additional service related costs and to apply for these alongside the research grant."

This means that researchers can work with community pharmacists to identify these costs and get them funded, she reports. (Research for Patient Benefit is described in the DH's Best Research for Best Health national strategy for health research announced in February.)

Professor Blenkinsopp goes on to argue that the Australians have shown the way forward in pharmacy-based research. "In Australia the pharmacy profession and the government agreed a strategy in which research is funded by government on the understanding that services will be funded if justified by the results. It's been very successful, and with the pharmacy white paper I think there's an opportunity to do something similar in the UK."

## The facts

- Good evidence showing that various kinds of pharmacy interventions can be effective in public health terms.
- The strongest research is in smoking cessation, diabetes detection and management, emergency hormonal contraception and immunisation against flu.
- However much more research needs to be done at the pharmacy level to provide the evidence to make pharmacy's case across a broader range of health areas.
- The climate is said to be more favourable for pharmacy research, due to the Research for Patient Benefit programme and the Department of Health's new national strategy Best Research for Best Health.

**References**


- Public Health Link (2009) The contribution of community pharmacy to improving the public's health: summary report of the literature review [online] http://tinyurl.com/dc8neb
- Department of Health (2009) Best Research for Best Health [online] http://tinyurl.com/cjluyu

# A Practical Approach
## Recurrent respiratory infections

**Brenda, senior technician at the** Update Pharmacy, is dispensing a prescription for a course of ciprofloxacin for Mark Murphy. She notices that he has had similar courses about every three or four months for the last two years and decides to call pharmacist David Spencer's attention to it.

David reviews Mr Murphy's PMR, which shows that he is 65 years old and has regular scripts for salbutamol MDI and beclometasone 250mcg MDI. David recalls that Mr Murphy was diagnosed with late onset asthma some years ago. David goes out to speak to him.

"I see you've got another course of antibiotics," David says.

"Yes, I've got another of those chesty coughs. Doctor says I've got to expect them if I carry on smoking. Twenty a day since I was 12, I can't see myself being able to stop now," Mr Murphy replies.

"How's your asthma?" David asks.

"Not too good. I use the inhalers religiously, but I still get breathless and I think it's getting worse."

"Well let's check that you're using them properly," David says. He tests Mr Murphy with a dummy inhaler and finds that his technique is very poor.

David asks: "Do you wake up breathless or wheezing during the night, or do your symptoms vary from day to day?" Mr Murphy answers no to both.

"If you don't mind," David says, "I'm going to contact your doctor with some suggestions so you get more benefit from your medicines. And I also think your underlying problem might not be asthma."

**Questions**

1. What might Mr Murphy's underlying problem be if it is not asthma?
2. What clinical features distinguish asthma from this condition?
3. What were David's suggestions to Mr Murphy's GP?

**Answers**

1. Chronic obstructive pulmonary disease (COPD).
2. Asthma: Wheezing, chest tightness, shortness of breath and dry cough. Symptoms are intermittent and variable and provoked by triggers such as cold air or allergens. Symptoms may be worse at night and vary during the day, with a morning dip in PEFR. There may be a family history of asthma or other atopic conditions. The condition can start in childhood or adolescence, more rarely at a later age.
COPD: Symptoms are exertional breathlessness, which is persistent and progressive, wheezing, chronic productive cough. Frequent respiratory infections, particularly in winter. Nearly all sufferers are smokers or ex-smokers. Unlike asthma, night-time breathlessness and wheezing and diurnal variation in symptoms are uncommon. The condition rarely manifests under age 35.
3. Review of the patient's diagnosis, bearing in mind the possibility of COPD. In view of Mr Murphy's inhaler technique problems, inhalers should be reviewed and dry powder or breath-actuated devices should be prescribed for any inhaled medication.

This article can help in the following CPD competencies: **G1a, G1c, G1d, G1e, G2o, C1a, C1b, C1c, C3e** See http://tinyurl.com/68ox7b

C+D's A Practical Approach is supported by APOTEX UK LTD

Survival guide PART SEVEN

# Preparing for sale

How can you make the best of selling your pharmacy in the current economic climate? Anne Hutchings offers some advice

Your pharmacy is likely to be the biggest asset you will ever sell. You will only have one chance to get this right. Do things the wrong way and it could cost you many thousands of pounds. Some people have a cavalier attitude to selling their business and while this may have worked to a certain extent at the peak of the market, it is not so successful now.

## If you want to:

- achieve the best price for your pharmacy,
- agree terms and conditions of sale, which are favourable to you,
- have the sale progress through each stage quickly and with minimum stress.

## You need to:

1 **Adopt the right attitude**. This means being totally committed to the sale. You should therefore be 100 per cent sure that you are ready to sell the business.

2 **Be realistic** about the price you are likely to achieve for the pharmacy. Take professional advice on this and accept it. I have lost count of the number of pharmacists I speak to who, when I tell them my opinion of the value of their business, reply "but I want...". Often their figure is 20 to 50 per cent higher than the realistic market value. Over-price the business and kill the sale!

3 **Be proactive.** The only way the sale will progress quickly is if everyone involved is proactive. This means that you, your advisers (pharmacy agent, solicitor, accountant), your buyer and their advisers (solicitor, accountants, finance lender) all need to be committed to the sale and be prepared to work to time scales.

4 **Have an excellent team of advisers.** In the current economic climate I believe it is more important than ever to have a team of experts looking after your interests. They should consist of:

Pharmacy agent – A good agent will be there to advise and support you from day one to the [illegible] sale. They will advise on valuation, [illegible] business to appropriate buyers, [illegible] buyer's financial position and [illegible] the best price and terms for you.

# CREDIT CRUNCH SURVIVAL GUIDE


When the sale is agreed, the agent's work does not end. It is part of their job to try to ensure the sale progresses to completion as smoothly and quickly as possible, which involves a lot of liaison between all parties.

**Solicitor** – Why don't pharmacists appoint an experienced commercial solicitor? Well, to be fair, some people do, but unfortunately many do not. Perhaps the reason is cost or just that they feel comfortable with the local solicitor who dealt with their house conveyancing.

The sale of a business is very different to the sale of a house and requires a different area of expertise. We have seen it all, from the one-man band solicitors who don't have email facilities and go on holiday just before the sale is due to complete, to the solicitor who produced a two-page contract for a company share sale (a typical contract would be in excess of 50 pages).

Source your solicitor at the outset – if you wait for the sale to be agreed this inevitably results in delays while you decide which firm to use.

> "In the current market the seller needs to go the extra mile and be prepared for all the questions buyers will want satisfactory answers to"

**Accountants** – Depending on how complicated your pharmacy sale is, you will need advice from someone experienced in business sales. This particularly applies to company share sales. Your accountant may have provided an excellent service over the years dealing with your bookkeeping and annual accounts but this does not necessarily mean they can also handle the issues that arise on a pharmacy sale. Be aware of this and take advice elsewhere if necessary.

## Essential documentation

Make sure you have all the basic documentation ready before the business is put on the market. The following is a checklist of what you need:

- Three years' accounts, which are up to date.
- NHS statements for the last 24 months.
- Copies of VAT returns for at least the previous 12 months.
- Copy of the premises lease (if you own the freehold, obtain a copy of the freehold and also the lease).
- Energy performance certificate for the premises.

## Extras

What can you do to attract buyers? Look at your business from a different perspective, for example, what would you be looking for if you were buying the business?

## Buyers want:

- To know they are making a sound investment. In the current climate it is not just buyers who require this but also their financial backers.
- Potential to increase the turnover and profitability of the business. If you were starting all over again now, what would you do to increase the business? Make a list of all the areas with potential, such as provision of services, collections etc, and summarise the additional income you think could realistically be generated. Also have a look at your costs, in particular expenses that are particular to you, such as a company car. Strip out all costs a new owner would not necessarily incur and make the buyers aware of this.
- A business that they feel is safe from competitors. The 100-hour applications and supermarkets have posed the biggest threat in recent years. If you find yourself under threat from a new contract application, unless you are an expert on the legislation, consult someone who is and who can advise on your options.
- To be confident that the local doctors will still be there in the future. Speak to your local doctors and the PCT etc and find out if there are plans for the future that could affect your pharmacy.

If there are plans that could negatively impact your business, this does not mean that you can't sell it. You have two choices: either be prepared to drop the price to counteract the problem or keep the business if you think you can overcome the problem.

It is good practice to analyse where your prescriptions are coming from, ie the percentage from each of your local surgeries. You may find that the loss of a local doctor who is retiring or moving won't have a big impact as far as you are concerned.

Overall, in the current market, the seller needs to go the extra mile and be prepared for all the questions buyers will want satisfactory answers to.

**Anne Hutchings, Hutchings Consultants Pharmacy Brokers**
**Tel: 01494 722224**
**www.hutchings-pharmacy-sales.com**

**Missed any parts of the Credit Crunch Survival Guide? See all the articles at www.chemistanddruggist.co.uk/creditcrunchsurvivalguide**

# Weighing up a fat opportunity

EXCLUSIVE As GSK prepares to reveal its new 'P' weight loss aid to UK consumers, Sarah Thackray looks at how pharmacies can benefit


Tim Brooks

**GlaxoSmithKline Consumer** Healthcare aims to get the press and public talking about weight loss with its consumer launch of Alli (60mg orlistat) in the coming week.

In an exclusive interview, Tim Brooks, marketing director OTC Consumer Healthcare UK, spoke to C+D about the opportunities this clinically proven P licensed medicine provides for pharmacy.

Obesity is one of the biggest health challenges we face in our society. Almost one in four adults in England is currently obese and, if we carry on as we are, nine in 10 will be overweight or obese by 2050.

"The statistics are getting worse and if people are overweight when they are in their 20s, it is very hard to stop them being obese by the time they are 40," says Mr Brooks. "If we don't tackle obesity, the rapid growth in diabetes and other related problems could greatly impact on the health service in years to come."

Mr Brooks believes the weight management category has enormous potential in the UK because the need is so great. He predicts it will become a very important OTC medicine category in the UK in the next three years.

"Alli was introduced as a grocery brand in the US two years ago and it is now the seventh largest OTC brand," explains Mr Brooks. "In the UK it will be a P brand so it will always be sold by a health professional which I think is totally appropriate. Alli will only be available for people with a BMI of 28kg/m$^2$ and over.

"Essentially, this is opening up a new category in the UK as Alli is the only licensed over the counter product for weight loss with a prescription heritage.... It is going to be an incremental new opportunity for pharmacists, both commercially and in establishing their role within primary care," he says.

"One of the challenges for pharmacies since the pharmacy contract has been to try to make themselves a focal point and a place where people can go for broad based advice to help with their health and lives. The pharmacist can use Alli as an opportunity to get involved with broader conversations about people's health."

"Pharmacists are ideally placed to provide support for those who want to lose weight by offering help to individuals to make healthy lifestyle choices around diet and exercise, as well as signposting local services available for those seeking to reduce weight. Pharmacies can help to drive business by actively promoting the service in their local community."

GSK has invested heavily in pharmacy training as the company sees this as being crucial to the product's success.

"This isn't a standard problem/solution type category, therefore the training is even more in-depth," says Mr Brooks. "Technically, we could have launched the product earlier but we decided to take the time to offer training to 7,000 pharmacists and pharmacy assistants through face to face training at over 60 venues as well as distance learning online."

Mr Brooks compares weight management to smoking control when it comes to the potential it offers pharmacies. He explains: "Both categories are ultimately about lifestyle and behavioural change, which is very hard for anybody and more people fail than succeed in both areas.

"There is an opportunity for pharmacists to think differently: not just selling pills but actually promoting a way of helping people to change their behaviour."

## Case Study

**Alistair Murray, from Green Light Pharmacy in the London borough of Camden, explains how he plans to develop his weight management service**

**Do you run a weight management consultation service at the moment?**
Not as such. We have a referral scheme where we can refer people to Camden's active health team and we work with local charities. We identify people through the screening that we do with the local population where we discuss people's weight and BMIs. We refer them to an appropriate source which may be the GP or we just try to encourage behavioural change.

**How do you help with behavioural change?**
We organise walks from the pharmacy in conjunction with Camden PCT. Two groups go for a walk for an hour and a half around Regent's Park each week. Some people are referred by their GP but others just turn up and join in. We have posters up in the pharmacy to promote the walks. As part of signposting under the pharmacy contract, it means that we have got something that we are running ourselves rather than just saying 'contact your local PCT or GP'. We are able to give people a realistic suggestion of what to do based on some of the lifestyle advice that we give them.

**Will you capitalise on Alli to develop a profitable weight management service?**
Very much. Because we will be able to make money selling Alli, we will spend time sitting down and going through in-depth counselling with people, using the consultation room rather than just over the counter. We want to try and support people, especially in the early stages so they get off to a good start.

**How will you start weight loss conversations?**
We have a scales machine out in the pharmacy that can work out BMIs and we don't charge people to use it. That is going to be quite an easy way to start the conversation and we can do a quick check to see if their BMI is 28 or over so that it fits in with the Alli recommendations for use.

**Will you be combining Alli with MURs?**
This is a brilliant suggestion. If somebody is having problems with their weight or has diabetes or high blood pressure then it would be an option to look at Alli for a few people as a recommendation from an MUR. I will also use MURs to discuss how orlistat might be affecting any of their medicines.

**How will you promote the service in your area?**
We are looking at possibly joining forces with some local pharmacies to put adverts in the local press. It's going to be important to speak to the local GPs so that they know that they can refer people along to us.

Information on Alli and training at www.mypharmassist.co.uk

# Pharmacy push for Naturtint

Nature's Dream is expanding the distribution of its Naturtint hair colorants in UK and Irish pharmacies with the sales support of the Miles Group.

Naturtint Green Technologies is formulated to permanently colour the hair without using ammonia, resorcinol or parabens. The manufacturer describes the range as being 'chemically light' and gentle on the hair and scalp.

The 29 mixable shades are formulated with active vegetable and certified organic ingredients. The products are enriched with a blend of oat, soy, corn, coconut and wheat extracts.

Nutrideep, a protective cream, is also available to help protect the hair from external damage, while reviving and fixing the colour.

Free point of sale material and a dedicated trade and consumer helpline are available.

The range has a profit margin of 25 per cent and opening order deals are available.


**Prices:** Naturtint £8.99; Nutrideep £8.99/200ml
**Pip codes:** see C+D Monthly Price List or www.cddata.co.uk
Nature's Dream
Tel: 0845 601 8129

# Light up cold sores

Oris Beauty Products is launching into pharmacies a personal light device for treating cold sores.

Biostick is the size of a large pen and uses a low frequency light to treat the affected area.

The product emits 630nm normal red light, which the manufacturer says does not give off heat and does not hurt or burn the skin. It is used by placing against the sore with the sore in the centre of the light.

Price: £34.20
Oris Beauty Products (part of [illegible])
Tel: 0208 885 8016

## Products advertised on TV next week

**DulcoEase:** A, HTV, CTV, W, M, five, GMTV, Sat

**Hedrin:** five, GMTV, Sat

**Seabond:** All areas

**Seven Seas JointCare and Cod Liver Oil:** All areas

**Wartner:** All areas except LWT, five

**PharmaSite for next week: Panadol** – windows, **Panadol** – in-store **Panadol** – dispensary

A-Anglia, B-Border, C-Central, C4-Channel 4, five-Channel 5, CAR-Carlton, CTV-Channel Islands, G-Granada, GMTV-Breakfast Television, GTV-Grampian, HTV-Wales & West, LWT-London Weekend, M-Meridian, Sat-Satellite, STV-Scotland (central), TT-Tyne Tees, U-Ulster, W-Westcountry, Y-Yorkshire

# Opportunities in eczema?

Could the rise in the incidence of eczema finally prompt moves to make more use of the pharmacist's knowledge? Gavin Atkin reports

Figures published by the Journal of the Royal Society of Medicine have shown a big rise in both the incidence of eczema and in associated prescriptions.

This won't have surprised community pharmacists dispensing emollients and steroid creams every working day, but it has come as a surprise to many researchers in the area.

The orthodox view is that the rise in incidence observed in the post-World War II era stabilised some years ago, and is now on a plateau. But the new study presenting results from an analysis of the QRESEARCH database of health data from 525 general practices shows the incidence of eczema rising from 9.58 per 1,000 person-years in 2001 to 13.58 by 2005 – an increase of almost 42 per cent in just four years.

By 2005, eczema affected an estimated 5,773,700 individuals, who on average consulted a GP 4.02 times a year and a nurse 1.62 times a year. During the same period, numbers of eczema-related prescriptions increased by 56.6 per cent, reaching an estimated 13,690,300 prescriptions across England in 2005.

What lies behind these striking figures? The authors suggest various causes, including environmental changes, rising sensitisation rates and a higher prevalence of atopy, increasing awareness of allergic problems and of the availability of effective treatments among both health professionals and patients.

Increased use of soaps and detergents and centrally heated homes may also be relevant environmental factors, says Skin Care Campaign chairwoman and pharmacist Christine Clark.

"You can build a case for modern living conditions making it worse. We know that using soap and detergent personal washing products may have had an influence and that house mite dust affects this group of people," she says. Dust mites encouraged by warm homes secrete proteases that can make eczema worse by breaking down skin and allowing antigens to enter skin more easily.

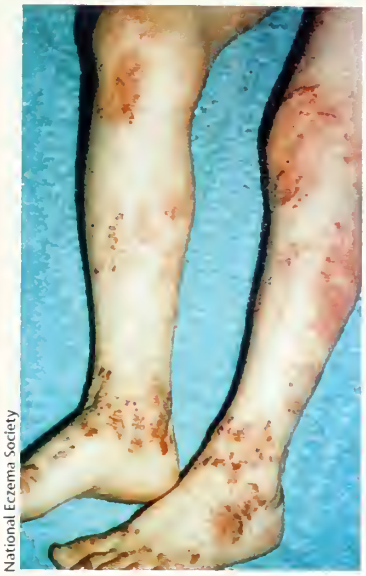
## What pharmacists need to know

- An analysis of health data from 525 general practices shows a large increase in eczema cases in just four years.
- Based on these figures, it is estimated that 5,773,700 suffered from eczema during 2005.
- On average, these individuals consulted a GP 4.02 times during the year, and a nurse 1.62 times.
- There has also been an increase in the numbers of prescriptions for eczema treatments.
- Patients with eczema may have difficulty accessing secondary care due to pressure on resources; experts in the area believe patients are therefore turning increasingly to GP practices and to pharmacies for help.
- The National Eczema Society has recognised the increasing role of pharmacy in this area, and plans to issue a booklet designed to help pharmacists to address eczema.

But what Dr Clark and others working in eczema find particularly interesting is the growth in primary care activity related to eczema during the study period.

The new figures relate to the period just after the government imposed the 14-day rule, which guarantees that any patient with a lesion suspected of being cancerous will see a specialist within 14 days.

Introduced in 1999, the regulation really began to bite in the study period, says Dr Clark, who argues that specialist centres with limited capacity may have seen potential skin cancers first in order to meet their targets. "This could have reduced the resources for conditions such as eczema and psoriasis," she says.



National Eczema Society

**Incidences of eczema have risen almost 42 per cent in four years**

National Eczema Society chief executive Margaret Cox puts it more strongly. "People with inflammatory skin disease have been struggling to get to secondary care," she reports. "They are seeking more help from GPs, nurses, alternative therapists and pharmacists."

For Ms Cox, the figures underline the pharmacist's role in reinforcing key messages important for patients and families with eczema. "Simple messages such as not using too much soap and the importance of moisturising can make a huge difference," she says, adding that the tendency for people with eczema to under-treat is another big issue, particularly where steroids are concerned.

"The thing we hear down our helpline time after time is that people are very reluctant to use an active treatment, so they leave it too late, they probably don't use enough, and they probably stop too early – all of which will result in the eczema not clearing and the whole process being repeated over and over again."

An interesting development to emerge is that the NES has recognised pharmacy's expanded role with MURs and pharmacists with special interests, and has decided to address the pharmacy sector in a new and much more direct way with a booklet to be distributed to pharmacists, and a new website. Pharmacists, it seems, can expect to be the subject of a significant campaign in the coming weeks.

Talking with Ms Cox about the pharmacist's role, it quickly becomes clear there is at least one more step she'd like to see to simplify the trial and error process by which patients are supposed to find an emollient that makes a difference to their disease.

In eczema, as we know, patients are supposed to try different emollients and other treatments until they find one that makes a big enough difference to their symptoms. It's a good principle, but making it work can be onerous – for each time one treatment proves to be less than perfectly successful the patient either has to return to the GP for a new prescription or pay to buy a new treatment they and their pharmacist feel they should try. And patients are making many visits to GPs – as many as four a year according to the QRESEARCH figures.

Ms Cox thinks this emphasis on GP prescriptions is presenting some significant barriers. "Our take is that even if people know that the trial and error approach is good in eczema, they can find it difficult to implement. It can be difficult to keep going back to the GP."

She argues that it would make more sense for pharmacists to be able to prescribe alternative emollients on the NHS rather than obliging patients to present to their GP repeatedly, and adds that pharmacists know much more about formulations than GPs in any case. "Pharmacists understand that a different type of topical treatment might be required to be effective," she says.

References are online at www.chemistanddruggist.co.uk

## Web resources

www.eczema.org
www.bad.org.uk

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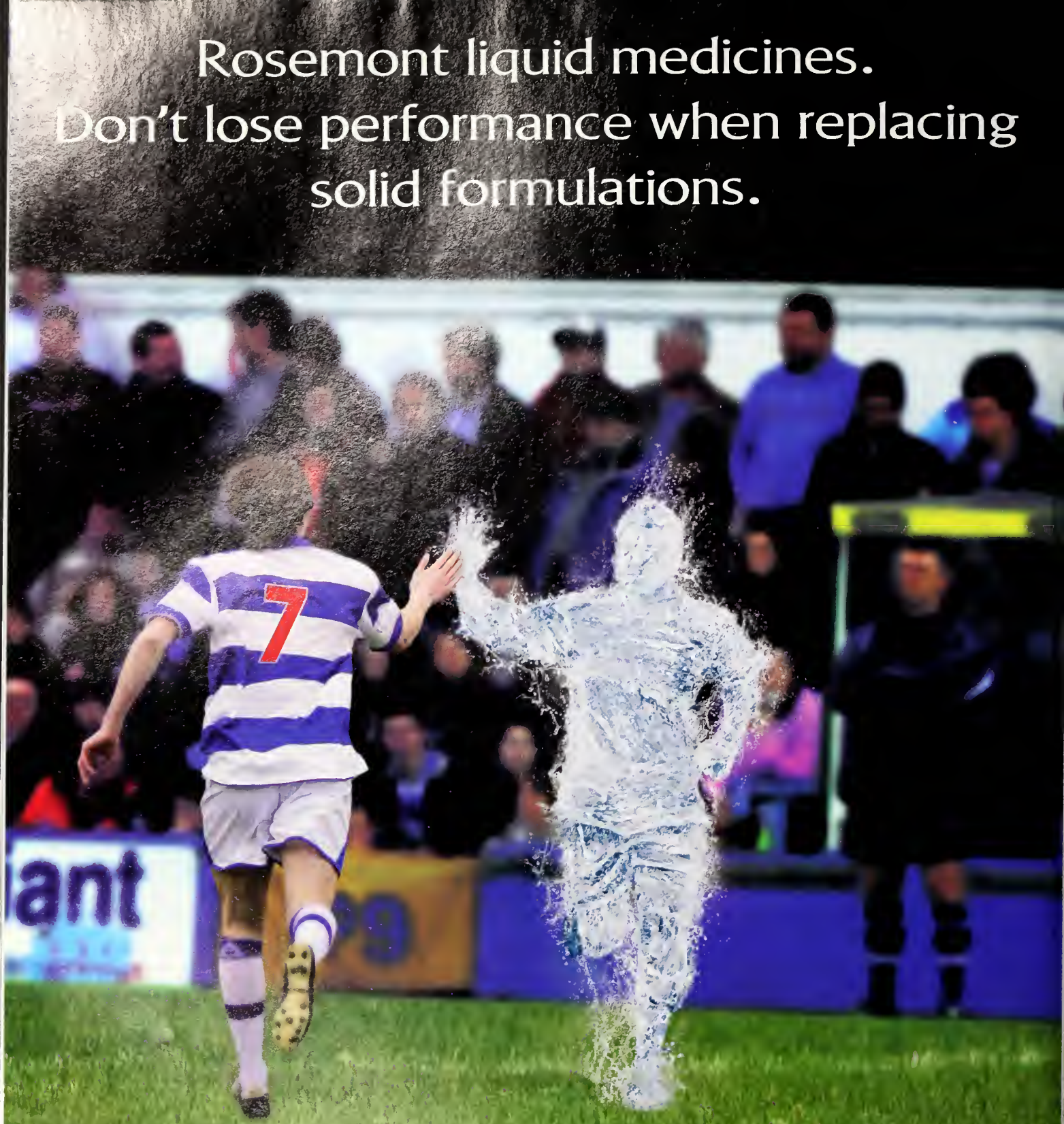

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Information about adverse event reporting can be found at www.yellowcard.gov.uk Adverse events should also be reported to Rosemont Pharmaceuticals Ltd on 0113 244 1400.

## CAREER LADDER

**At the Boots Centre for Innovation...**

Venture capitalist Ron Peterson (pictured) has been appointed managing director of the Boots Centre for Innovation.

Mr Peterson has been involved in the Swansea-based facility since it was founded in 2007, as the co-founder of the Centre's venture capital partner Longbow Capital LLP. He was "well positioned to lead the Centre forward in 2009", a spokesperson said, having in the past provided "valuable advice on how to progress ideas".

**At Asda...**

Asda was named Innovative Employer of the Year at the 2009 Oracle Retail Week Awards last month. The supermarket was celebrated for the "comprehensive suite of strategies and innovations" that put its people at the heart of the company's operations.

**At Sainsbury's...**

Sainsbury's employees netted up to £15,500 when two of the supermarket's save as you earn schemes matured last month. Ten thousand colleagues benefitted when three- and five-year schemes matured at a share price of £2.93, representing an increase of up to 28 per cent on savings.

## C+D Jobs

**New positions from Rowlands and Superdrug have been added to the jobs section of the Chemist+Druggist website. You can now search through more than 500 positions by going to www.chemistanddruggist.co.uk/jobs**

# Turning points

The key decisions and philosophies that have shaped the career of **Paul O'Hanlon**, Lloydspharmacy business development director

### Making my mark

After starting out in a health centre pharmacy in Manchester, I worked for a number of small groups, building up my experience of different types of pharmacy. I really enjoyed the interaction with the patients but was frustrated when I was tied to the dispensary bench. Then I joined Medimark, a small group of about 15 pharmacies based in Yorkshire; I was its operations director while it expanded for five years. The bit of pharmacy that most stimulates me has always been the management and commercial sides, and I think they recognised that.

### International relations

When Medimark was sold in 1995, bringing me into Celesio and what would become Lloydspharmacy, Celesio gave me the opportunity to tackle the emerging market of Ireland.

I was made MD of the Unicarepharmacy group, and we built it from scratch into a proper retail pharmacy division – going from about 20 pharmacies to 63.

It was a really exciting time, as it's seeing things built, achieved and progressed that motivates me. The highlight of my career has been seeing Unicarepharmacy go from a basic, newly put together company into something that had a proper structure and was going somewhere.

Just as I left the company, we were recognised as one of the top 10 companies to work for in Ireland and I was really chuffed because that came from the staff. When you move on you have really got to let others do it their own way – but I do watch quietly from the sidelines!

### Homeward bound

After four-and-a-half years the time had come to return because it was quite difficult with my family still in the UK, and I took over the clinical business development in Lloydspharmacy. Last year we developed Evolution Homecare and after appointing its MD in January, I came back to join the Lloydspharmacy board.

It's interesting at the moment. I have the retail business development on one side and ethical purchasing on another.

I also still have the clinical business development department, where I'm trying to push the boundaries of what we're doing, such as screening services and out-patient dispensing.

### Seizing the day

I try to get in early to clear my emails, but I can't say I'm 100 per cent successful! Today started with an interview for a new person for the team, and the rest of the morning was spent reviewing our strategy for purchasing. Lunch was followed by another hour or so clearing emails and check-ups with one or two people and the end of the day will be a meeting with Celesio and AAH, where we're discussing options for improving our delivery service.

I enjoy my job. If I didn't, I wouldn't do it. I enjoy the variety and the mental challenge because nothing is easy. I also like the people; it's great when I see the team succeed, that's really important to me.

Sometimes the pace of change is too slow for me, but we're a very big organisation and organisational change is never easy. That would be my biggest frustration – we're never moving as fast as I would like.

### Focus and reflection

At the moment, my key objective is making sure I have the right team for each element of the role; that they will have very, very clear objectives, not just for the next 12 months but two or three years; and that those objectives are also aligned with the whole business.

I try to take stock – reflection is so important in the role. The more you reflect on things, the more experienced you become. About every six months I need to have a thorough review of where we have got to, but it's an ongoing process – I'd be really upset if I got to the six months and thought, we're going the wrong way. It couldn't work like that.

### Knowing what I've learned

Have fun. It does make a huge difference to your day; it's something I try to impress upon all my team. Young pharmacists have got to get off the dispensary bench and with the patients. It's very easy to get bored and tied to the dispensary bench, but the pharmacy of the future is about the clinical agenda, not the dispensing agenda. And work hard. You get nothing for nothing.

**CAREER TIP of the week**

**"By mirroring the words the employer uses in their job advert, you can ensure your CV immediately catches their eye. You are in effect using the same words to describe yourself as the employer has used to describe their ideal candidate."**
From Brilliant Job Hunting, by Angela Fagan
www.chemistanddruggist.co.uk/booksforjobhunters

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Essential personal skills to include excellent interpersonal and written communication skills, presentation skills, an ability to work as part of a team, organisational ability and a high level of enthusiasm.

If you would like to apply for this position, please send your CV and covering letter to:

Amanda Haddock
PA to Directors
Numark Limited
5/6 Fairway Court
Amber Close
Tamworth
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Or email amanda.haddock@numark-central.co.uk
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PHOENIX Healthcare Distribution,
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Runcorn WA7 3DJ
**scongleton@phoenixmedical.co.uk**

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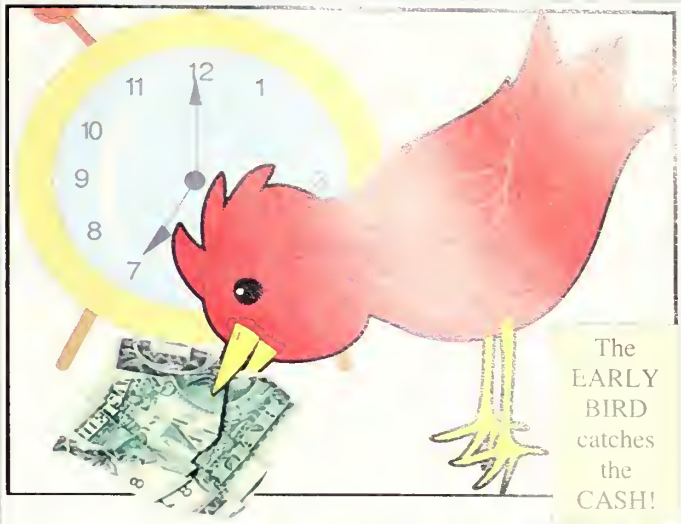


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# postScript

Mike Hewitson

## The not-so secret diary of a new pharmacy owner

**Mike Hewitson is a glutton for punishment. In the midst of economic downturn, he has bought his first pharmacy in deepest, darkest Dorset – 100 miles from his former Cheltenham home. As if that weren't enough, he now has newborn daughter Gracie keeping him awake at night. Follow Mike's fears, frustrations and step-by-step successes as the new owner of Beaminster Pharmacy.**

> "One of my employees came in on her day off to see if she still had a job"

"Can I sign the petition?"

"Er, what petition is that, then?"

"To stop you being taken over by Boots!"

Although I am quite accident prone, I never thought I could unintentionally sell my pharmacy. But this was not the only conversation I had of this type over the space of a couple of days. After the first, I was confused; after the third I was worried.

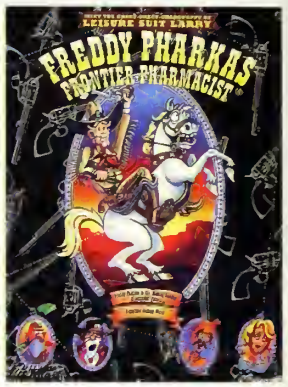
Maybe I had sold my business without realising it? I checked the contents of the drinks cabinet: no sign of any serious deficits. I could vaguely recall the day, month and year, and knew who the Prime Minister was – so no sign of any major cognitive defects, either. Yet one of my employees even came in on her day off to see if she still had a job next week. If you, like me, are even more confused than normal I wouldn't blame you, so let me start at the beginning...

As April loomed large we had been making a final push to ensure we had our 125 completed patient satisfaction surveys and, with only about 20 to go having given out nearly 300, I asked a regular if he had filled one out. "No," he said, "what was that in aid of?"

"To make sure we're doing our job properly," I replied, "and also so that nobody else can try to open a pharmacy by saying we aren't." It was a fairly light-hearted, off the cuff remark, but all of a sudden people were very worried about the future of their highly valued local pharmacy.

Despite the unnecessary confusion, I have taken this interesting episode as a great endorsement of the job we're doing.

## Pharmacy at a new frontier




Imagine a computer game about pharmacy. Now imagine it's set in the Wild West and you play a one-eared gunslinger-turned-pharmacist. And make sure, between OTC sales, you can date a sheep named Olga.

If, somehow, you can picture this bizarre combination, you're probably coming close to a weird little computer game PostScript discovered while cleaning out its hovel.

Freddy Pharkas: Frontier Pharmacist is a comic adventure game released by Sierra in 1993. The player controls the titular hero as he battles ruthless robber barons, cures flatulence epidemics and saves the town from a snail stampede.

The game begins with a five-minute cowboy ballad, justifying pharmacy as the profession of choice for gunslingers: "He'd be better off, he reckoned; with the lifelong dream that always beckoned; pestles, not pistols, and pharmacology."

Within an hour of play PostScript was totally bemused: the first puzzle involves sobering up the town doctor to clarify an illegible script.

You then need to resolve a prescribing error that otherwise results in a very hirsute brothel madam, before flogging pile cream to a prospector.

As the game's plot unfolds, Freddy labours to save the town from a cornucopia of disasters in increasingly bizarre fashion: he extinguishes fires using playground swings and hurls sharpened prosthetic ears at bandits.

Even the game's manual has a quirky sense of humour. The back of the tome contains a fictitious pharmacopeia of quack remedies and joke advice.

As an adventure game, Freddy Pharkas is average; as a pharmacy simulator it's surreal. But it stands alone in promoting the profession to a different audience. Freddy, PostScript salutes you.

## Raiders of the Lost Archive

**This year is C+D's 150th birthday. Join us as we explore the stories that interested pharmacists back in 1859**

1859-2009

"Galvanism! Its salutary effects now brought within the reach of everyone," screamed an ad in the December 1859 issue of C+D.

And what is galvanism, you ask? Basically it's casual electrocution, claiming to cure everything from deafness to gout, including epilepsy, indigestion and 'female complaints'.

Patronised by European heads of state (Queen Victoria, the Empress of Austria and Napoleon III were apparently fans), "Pulvermacher's patent galvano-anti-rheumatic chain-band" promised to bring the "miraculous power of galvanic electricity" into every home.

One hundred and fifty years on, PostScript can confidently say it failed miserably.

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Levonelle One Step is launching its first ever TV campaign in April, raising awareness of emergency contraception and its availability at pharmacies among an even greater number of women. **Stock up to meet demand.**

**Levonelle® One Step™ 1500 microgram tablet**
**Prescribing Information** (Refer to the Summary of Product Characteristics (SmPC) before prescribing) **Presentation:** One tablet containing 1500µg levonorgestrel. **Uses:** Emergency contraception within 72 hours of unprotected intercourse or failure of contraception. Not recommended for young women under 16 without medical supervision **Dosage and administration:** One tablet taken as soon as possible, preferably within 12 hours, and no later than 72 hours after unprotected intercourse. Vomiting, or other causes of malabsorption (such as Crohn's), might impair the efficacy of Levonelle One Step. If vomiting occurs within 3 hours of taking the tablet, another tablet should be taken immediately. Use at any time in the menstrual cycle unless period is overdue. After use, advise using barrier methods until next period. Regular hormonal contraception can be continued. **Contraindications:** Hypersensitivity to any of the ingredients of the preparation. **Warnings and precautions:** Levonelle One Step is suitable only as an emergency measure. Advise women presenting for repeat courses to consider long-term methods of contraception. Levonelle One Step does not prevent a pregnancy in every instance. If timing of intercourse is uncertain or occurred more than 72 hours earlier, conception may have already occurred. Following treatment, if the next menstrual period is abnormal or more than five days late, women should be referred to a doctor so that pregnancy may be excluded. If pregnancy occurs, evaluate for ectopic pregnancy. Ectopic pregnancy risk is low. Ectopic pregnancy may continue despite uterine bleeding. Explain importance of follow-up appointment and possible alteration to timing of next period (few days earlier or later). Exclude pregnancy in users of regular hormonal contraception if no bleeding occurs in the next pill-free period. Not recommended for women with severe hepatic dysfunction. Emergency contraception does not protect against sexually transmitted infections. Repeat administration within a menstrual cycle is not advisable due to possible disturbances of the cycle. Efficacy might be impaired in women with malabsorption syndromes or by interaction with concurrent drugs including barbiturates (e.g. primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St John's wort), rifampicin, ritonavir, rifabutin, griseofulvin. Medicines containing levonorgestrel may increase the risk of ciclosporin toxicity. Women with malabsorption syndromes or on interacting medicines should be referred to a doctor. Levonelle One Step contains 142.5mg lactose. Take this into account for women with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. Epidemiological studies indicate no adverse effects of progestogens on the foetus but there is no data available for doses greater than 1.5 mg levonorgestrel. Animal studies showed virilisation of female foetuses at high doses. Levonorgestrel is secreted into breast milk. Advise breast feeding women to take the tablet immediately after a breast feed. **Side-effects:** Nausea, low abdominal pain, fatigue, headache, dizziness, breast tenderness, vomiting and diarrhoea. Bleeding patterns may be temporarily disturbed. **Trade price:** £13.83 per tablet **Legal classification:** P **PL Number:** PL 05276/0020 **PL Holder**: Medimpex UK Limited, 127 Shirland Road, London, W9 2EP **Distributor:** Schering Health Care Limited, The Brow, Burgess Hill, West Sussex, RH15 9NE. Levonelle One Step is a registered trademark of Bayer Schering Pharma AG (formerly Schering AG). Date of revision: March 2009

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9LVN16 Date of preparation: April 2009